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Guidance for the Reregistration of Pesticide Products Containing Phorate as the Active Ingredient

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GUIDANCE FOR THE REREGISTRATION OF MANUFACTURING-USE AND CERTAIN END-USE PESTICIDE PRODUCTS

CONTAINING

PHORATE
(057201)

CAS 298-02-2

Case No. 0103

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

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Workgroup

Gary Ballard	(BUD/PQUA)
Bill Boodee	(RCB)
Dave Brassard	(BUD/INDEX)
George Ghali	(TOX)
Marilyn Mautz	(RD)
Pat Ott	(EAB
Ann Stavola	(EEB/SIS)

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INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all pesticides as expeditiously as possible. Each registrant of a manufacturing use product of the active ingredient who wishes to continue to sell or distribute that product must apply for reregistration.

To fulfill this Congressional mandate, we have established the Registration Standards program which will review all pesticide active ingredients first registered before January 1, 1977. These pesticides will be reviewed in use clusters which are prioritized on the basis of a ranking scheme giving preference to pesticides used on food and feed crops.

The Registration Standards program involves a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing studies which may not have been required when the product was initially registered or studies that are now considered insufficient. Our reassessment results in the development of a regulatory position, contained in this document, on each pesticide and its uses. The regulatory position may require the registrant to modify product labels to provide additional precautionary statements, restrict the use of the pesticide to certified applicators, provide reentry intervals, modify uses or formulation types, specify certain packaging limitations, or other requirements to assure that proper use of the pesticide poses no potential adverse effects to human health or the environment.

The scientific review, which is not contained herein but is available upon request, concentrates on the technical grade of the active ingredient and identifies missing generic data. However, during the review of these data we are also looking for potential hazards that may be associated with the formulated (end-use) products that contain the active ingredient. If we find serious concerns, we will bring formulated products under the provisions of the Registration Standards program to the extent necessary to protect the public.

EPA has the authority under FIFRA §3(c)(2)(B) to require that certain registrants submit generic data that will answer our questions regarding the hazard that may result from the intended use of the pesticide under review. Further, §3(c)(2)(B) provides that these data are to be submitted by those registrants who do not qualify for the formulator's exemption [FIFRA §3(c)(2)(D)]. Normally, this means that the registrants who are responsible for filling the data gaps are the manufacturing-use product producers (basic suppliers of the active ingredient). However, end-use producers will not qualify for the formulator's exemption if the source of their active ingredient: (1) is not registered with EPA, and/or (2) is produced by the registrant's firm, or a firm which has ownership in common with the registrant's firm. These end-use producers can qualify for the formulator's exemption if they change their source of supply to a registered source, provided the source does not share ownership in common with the registrant's firm. If the end-use product registrant decides to switch sources, a new Confidential Statement of Formula, EPA Form 8570-4, must be submitted to the appropriate Product Manager within 90 days of receipt of this Guidance Document. The chart on the following page shows what is generally required of those who do and do not qualify for the formulator's exemption in the Registration Standards program.

If you decide to request the Agency to discontinue the registration of any of your products subject to the reregistration requirements of this Guidance Document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following pages within the timeframes outlined. EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product if you fail to comply with the requirements set forth in this Guidance Document.

This Guidance Document will be supplemented by EPA with additional information about compliance with data support requirements. In Union Carbide Agricultural Products Co. Inc., et. al., vs. Ruckleshaus, EPA was enjoined from permitting or implementing any use of data where the submitter's compensation is to be determined under §3(c)(1)(D) of FIFRA. EPA is assessing the implications of the injunction for the reregistration process. Because this situation is currently unresolved, EPA has decided to proceed with the requirements in this Guidance Document which do not relate to compliance with the §3(c)(1)(D) provisions and to supplement the Document with additional guidance when circumstances permit. Failure to comply with the provisions of the subsequent guidance will also result in issuance by EPA of an intent to cancel the affected product registration(s).

Registrants are reminded that §6(a)(2) of FIFRA requires you at any time to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible unreasonable adverse effects.

PRODUCTS SUBJECT TO THE REGISTRATION STANDARDS PROGRAM	ACTION(S) REQUIRED TO MAINTAIN REGISTRATION
I. Products That Do Not Qualify For The Formulator's Exemption	
A. Single Active Ingredient Products*	These products must be reregistered. To obtain reregistration, labeling, packaging and data requirements must be satisfied in accordance with the Registration Standards Guidance Document.
B. Multiple Active Ingredient Products	These products will not be reregistered at this time. However, generic data required to continue the registration of the active ingredient under review, as described in the Registration Standards Guidance Document, will be required and some labeling precautions may also be required.
II. Products That Do Qualify For The Formulator's Exemption	Only when additional restrictions or labeling are needed to protect man or the environment will these products be subject to the Registration Standard requirements. Affected products will be dealt with in a variety of ways, including but not limited to the Label Improvement Program and special intent to cancel notices.

* End-use products of registrants who also produce a manufacturing-use product will not be required to be reregistered provided that registrant fulfills the requirements specified in the Guidance Document for manufacturing-use product(s). Such end-use products will be subject to the labeling changes required for products in "II" above. If there are no manufacturing-use products registered by any company end-use products will be required to be reregistered.

NOTE: If all registrants in "I" above fail to meet the requirements in I-A and B above, then the registrants in "II" lose their right to qualify for the formulator's exemption and become subject to the requirements in I-A and B.

I. Regulatory Position

A. Introduction

This Registration Standard describes the regulatory position of the Environmental Protection Agency (EPA) on manufacturing-use products (MUP's) containing the insecticide-nematicide, phorate as a sole active ingredient. The Agency's position is based on an evaluation of all registered uses of phorate and registered MUP's with phorate as an active ingredient.

This document provides the rationale for the Agency's position and the criteria for registration that result from it. It also discusses labeling requirements and tolerances. Finally, it considers "Special Local Needs" registrations, authorized by Section 24(c) of the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), as amended, in addition to federal registrations granted under Section 3 of the FIFRA. Future products that differ appreciably from those described in this Standard may require an amendment to this Standard to reflect the difference. No new uses for phorate will be considered until the human and environmental concerns raised in this Standard are satisfactorily resolved.

B. Use Profile

Phorate is the common name for 0,0-diethyl S-[(ethylthio) methyl] phosphorodithioate. Trade names and other names include Thimet, Rampart, Vegfru Foratox and AC 3911. The chemical is manufactured in the U.S. by American Cyanamid Co.

Phorate, a plant systemic organophosphate chemical, is principally used as an insecticide for the agricultural crops, field corn, potatoes, cotton, sugarbeets, soybeans and wheat. Additional registered uses include the agricultural crops, alfalfa, barley (irrigated), beans, Bermuda grass, sweet corn, hops, lettuce, peanuts, rice, sorghum, sugarcane and tomatoes, and the ornamental uses for nursery stock and in greenhouses. None of the currently registered products containing phorate are specifically registered for use in or around the home.

Phorate is usually applied to the soil at planting time or as a side dress during cultivation in early postemergence. Foliar application of granules (to be applied into the whorls of the plants) may occur in early postemergence to crops such as corn and sorghum. Although phorate products are registered for ground or aerial application, most of them are applied by ground equipment.

Phorate is also registered for use as a nematicide on commercially-grown ornamentals (azaleas, boxwood and lilies) to be applied as a granular ground application either as a broadcast treatment over the plants or as a side dress over the root zone. In addition, phorate is also registered for use in greenhouses in the production of the commercially-grown ornamentals, carnations, chrysanthemums and dahlias.

Most of the registered end-use products containing phorate are granular formulations and range from 0.15% active ingredient to 20% active ingredient. Some of these formulations are phorate-fertilizer formulations. Phorate is also registered as emulsifiable concentrate (EC) formulations ranging from 65.6% (6 lb/gal) to 90% (8.7 lb/gal) active ingredient (for use on Bermuda grass grown for seed as an aerial or ground application; for treatment of cottonseed and for soil application for corn at planting time).

There are currently three registered MUP's containing phorate as a single active ingredient. All three of the MUP's contain 85% phorate. A total of 39 end-use products containing phorate are registered under Section 3 of FIFRA; 29 contain phorate as a sole active ingredient and 10 contain phorate in combination with other active ingredients. Five are registered under Section 24(c) of FIFRA (Special Local Need Registration).

C. Regulatory Position

Based on a review and evaluation of available data and other relevant information on the chemical, the Environmental Protection Agency has made the following determinations regarding phorate:

1. Manufacturing-use pesticide products containing phorate as a sole active ingredient may be registered

for sale, distribution, and use, subject to the terms and conditions specified in this Standard.

2. The Agency is concerned about possible dermal and inhalation exposure to workers because of phorate's high acute toxicity. In order to more accurately assess this potential risk, reentry studies (dermal exposure, inhalation exposure, foliar dissipation and soil dissipation studies) are required to be submitted. An interim reentry interval of 24 hours is being required under this Standard pending receipt and evaluation of these studies.

3. Based on the present use patterns and application practices, there would appear to be little likelihood of exposure to workers resulting from the handling and use of the phorate granular formulations. However, should the granules fracture during shipping and handling, an inhalation and dermal exposure hazard to handlers and other workers subject to prolonged exposure may occur. Therefore, product integrity studies on the typical end-use phorate granular formulation are being required to assess this possibililty. Depending on results of these studies, additional precautionary labeling and/or other protective measures, as appropriate, will be implemented. In addition, a subacute inhalation

exposure study (21-day rat) and a subacute dermal study may be required.

4. All currently registered end-use products containing phorate warrant classification as restricted use due to phorate's extreme toxicity and potential for exposure. The Agency is limiting phorate's use to certified applicators or workers under their direct supervision.

   Granular formulations containing less than 5% phorate are classified as restricted use pesticides pending receipt and evaluation of additional data. Refer to section D, item 5, of this chapter for a further discussion and rationale regarding this classification determination.

5. In view of the fact that certain oxidation products of phorate are considerably more toxic that phorate itself, and, considering the fact that the oxidation products were previously discounted in assessment of the current tolerances, the actual burden in the human diet may be far greater than it appears to be. However, pertinent residue chemistry and toxicological data are lacking and the Agency is unable to complete an exposure assessment of human dietary intake. These data, as requested in the accompanying

Table A, are needed to establish acceptable daily intake levels of the oxidation metabolites and to reassess the present tolerances in terms of the nature and magnitude of these metabolites. Refer to Section H, Tolerance Reassessment. Pending receipt and evaluation of data, no additional tolerances will be granted.

6. The available field studies and reports of bird kills corroborate the findings of the laboratory studies that phorate is very highly toxic to birds and small mammals. The hazard can result directly from ingestion of granules or indirectly by consumption of invertebrates, vegetation, or water containing phorate residues. Available data are not sufficient to assess the significance of this hazard, i.e., to determine if significant population reduction will occur. Full field studies including population monitoring are required as well as an avian reproduction study. Based on the fact that the metabolites of phorate are more toxic than phorate itself, secondary poisoning studies are needed for one mammal and one avian species.

7. The available laboratory studies and reported fish kills demonstrate the very high toxicity of phorate

to freshwater and estuarine organisms. Phorate residues were detected in ponds in cornfields in Illinois and streams in California at levels that can produce acute and chronic toxicities in aquatic organisms. Additional data are needed, however, before the Agency can complete a full assessment of this hazard potential. These data include full field studies with population monitoring as well as the environmental fate data as specified on the accompanying Table A. A fish life-cycle study and an aquatic organism accumulation study may also be required depending on results of lower tier studies and environmental fate data.

8. Rather than the traditional product by product labeling approach to protect endangered species, the Agency has decided to adopt a generic (cluster) approach for addressing endangered species concerns associated with the uses of pesticides. The Office of Endangered Species, the agricultural community and the Agency believe the conventional labeling approach is inadequate to properly inform the users on how to protect the endangered species and at the same time use the product to the greatest benefit.

Appropriate labeling for the protection of the species determined to be in jeopardy is being developed in conjunction with the generic approach rather than under this Standard. This generic approach, which entails the analysis of the effects of all pesticides on endangered species on a crop by crop basis, rather than a chemical by chemical approach, is being developed in cooperation with Federal and State enforcement Agencies, the Office of Endangered Species (OES), the U.S. Department of Agriculture (USDA), the National Agricultural Chemical Association (NACA) and both the state and county extension services. Thus, the labeling developed under this approach will encompass all endangered species associated with use of pesticides on that particular crop.

The Office of Endangered Species, Fish and Wildlife Service, has issued biological opinions for the corn, cotton, sorghum, soybeans and small grains clusters. The continued existence of the Atwater's greater prairie chicken, Aleutian Canada goose, Everglades kite, slackwater darter, woundfin, freshwater mussels, valley elderberry, longhorn beetle, delta green ground beetle and Kern primrose sphinx moth is jeopardized by the uses of several pesticides, including phorate, on the above crops. These are the only clusters that have been completed, and it may be determined that more species are jeopardized by phorate when other clusters are completed. It is presently anticipated that appropriate labeling will be developed in time for the 1985 growing season for these five crops.

9. Phorate has some potential to leach through soil and contaminate ground water, particularly where soils are sandy and aquifers are shallow. Simulation of the leaching potential of phorate using the Pesticide Root Zone Model (a computer model which predicts movement through the root zone and the unsaturated soil zone based on chemical and soil properties) predicts some mobility in sandy soils but none in loam soils under typical phorate use conditions. Because of lack of sufficient data regarding the environmental behavior of phorate, the Agency is unable to completely evaluate the leaching potential. Additional studies are being requested on an accelerated basis; these studies include hydrolysis, metabolism, and mobility studies, and in particular a field dissipation study, which is to be carried out in a potato growing area of Long Island, New York.

10. Registrants must provide or agree to develop additional data, as specified in Tables A and B located in Chapter IV of this document, in order to maintain existing registrations or to permit new phorate registrations.

11. The Agency has determined that no new uses for phorate will be considered until the human and environmental concerns raised in this Document are satisfactorily resolved.

D. Regulatory Rationale

The Agency has determined that it should continue to allow registration of phorate after considering the following:

1. The stringent label warning statements reflecting the high acute toxicity to humans will minimize the acute hazards associated with the oral, dermal, inhalation and ocular routes of exposure to users of products containing phorate.

   Such statements include directions for use of protective clothing including gloves, goggles and a mask or respirator.

2. The worker protection statements imposed under the Farm Workers Protection Program (PR Notice 83-2), and the interim reentry interval of 24 hours imposed under this Standard together with the required use of gloves, and protective clothing described in this Standard will minimize the acute hazards to farmworkers and to handlers and users of the end-use products.

As described in Section C Regulatory Position, additional data are needed, and are required, under this Standard in order to more fully assess the hazard to humans through the dermal and inhalation routes of exposure.

3. Review of the available chronic toxicity studies indicate that phorate is not considered an oncogen (based on oncogenicity studies in both the rat and the mouse); phorate did not produce teratogenic effects in the rat; and the chemical was not shown to be mutagenic in several in vitro (microbial and mammalian cell) tests, and in vivo dominant lethal study.

4. It is not the Agency's policy to cancel or to withhold registration merely because data are missing or inadequate [see FIFRA Sections 3(c)(2)(B) and 3(c)(7)]. Rather, publication of this Standard provides a mechanism for identifying data needs,

and registration of phorate under this standard allows for the upgrading of labels during the period in which the required data are being developed. These data will be reviewed and evaluated when they are received and the Agency will determine at that time whether they will affect the registration(s) of phorate.

5. The expansion of the restricted use classification to include all current registered end-use products containing phorate will ensure that the chemical will not be available for use by the general public pending receipt and evaluation of additional data.

   As specified elsewhere in this Standard, the Agency has determined that all end-use phorate products warrant restricted use classification. Granular products containing less than 5% phorate are classified as restricted use pesticides pending receipt and evaluation of additional data.

Rationale for Restricted Use Classification

All emulsifiable concentrates (EC) 65% or greater and all granular formulations for use on rice were previously restricted by regulation on August 1, 1979 (40 CFR 162.31).

Classification for the EC formulation was based on the high dermal toxicity of the formulations and the residue effects on avian and mammalian species (foliar application only); and for the use on rice was based on the effects on aquatic organisms. These restricted use classifications will remain in effect.

There are no EC formulations containing less than 65% phorate currently registered. Should such products be proposed for registration as end-use products under the Standard, they will be considered to be restricted use pesticides.

Though the granular formulations containing 5% or more phorate were previously proposed for restricted use on August 1, 1979 (44 FR 54219), the Agency never promulgated a final rule classifying these formulations. The Agency has since indicated that its preferred method for classification is through the reregistration process, thus all granular formulations 5% and greater are being restricted through this Standard.

All products containing phorate released for shipment after September 1, 1985, must be labeled for restricted use. All products which are in channels of trade after September 1, 1986, must be labeled for restricted use.

The September 1, 1985, date for products released for shipment provides time for States to certify applicators and also assures that most products used in the 1986 growing season are classified as restricted. Requiring all products still in channels of trade after September 1, 1986, will prevent stockpiling by dealers and distributors and assure that all products available for the 1987 growing season are restricted.

The restricted use labeling for the EC formulation 65% or greater and for the use on rice previously restricted is to remain in place.

Classification considerations are based on the toxicity categories in §162.11(c). The principal human effects triggers for chemicals used in non-domestic settings are the Toxicity Category I criteria, i.e., acute dermal LD_{50} - 200 mg/kg; acute inhalation LC_{50} - 0.2 mg/l; acute oral LD_{50} - 50 mg/kg. Following the identification of candidates based on these criteria, §162.11 calls for an evaluation of label adequacy. Section 162.11 also requires an evaluation of other information such as accident history, epidemiology studies, etc., to determine if a formulation/use should be restricted. The Agency has determined that the 5% and greater granular formulations failed to meet the label adequacy test for general use as described in §162.11(c)(3). Specifically, the Agency determined that:

1) Failure to follow directions for use and/or proper disposal, even in a minor way, may result in serious adverse effects to individuals through accidental ingestion, breathing dust from open bags, or by failure to wear rubber gloves and/or undergo proper washing [(§162.11(c) (3)(ii)].

2) Failure to follow directions to not use or store in and around the home or garden may result in adverse effects for individuals contacting treated surfaces or eating treated vegetables [(§162.11(c)(3)(ii)].

3) Failure to follow common use practices in loading or cleaning equipment could result in serious adverse effects to the applicator [(§162.11(c) (3)(iii)].

The current registered uses of phorate are limited to agricultural crops and to commercially grown ornamentals. There are no domestic uses.

In the evaluation of the granular formulations (5% phorate or more) for classification purposes, the Agency has also considered the effects on avian species resulting from use of these formulations. The Agency has determined that, in addition to human effects, these formulations are to be classified restricted use formulations based on effects to avian species. This determination was made based on the very high acute oral toxicity to avian species (less than 50 mg/kg); results of available simulated field studies; and the reported incidents of bird kills resulting from use of such formulations. Four such reports have been recorded resulting in a total of 2,822 bird fatalities. The consumption of phorate granules and phorate contaminated water has been implicated in these reports.

As noted previously in this Document, all granular formulations containing less than 5% phorate are also being restricted under this Standard. Based on extrapolation of available acute oral toxicity data in our files, only formulations containing 2.8% or more phorate would theoretically have an acute toxicity of 50 mg/kg or less, and thus would be candidates for restricted use classification.

The Agency is, however, requiring that all granular phorate formulations below 5% bear restricted use labeling pending receipt and evaluation of the data required under this Standard (refer to Data Table C). Reports generated from the Pesticide Incident Monitoring System (PIMS) support the Agency's determination. In three reported cases of bladant misuse, food items (specifically, peanuts and beans) had been mixed with granular phorate and ingested by nine children, two of whom died. In addition, several cases of farm animals dying from ingesting stored granular pesticides, including phorate, have been reported. There have also been several reported cases of adverse human health effects resulting from the use of phorate granular products during bagging, mixing/loading and application of the pesticide, one of which resulted in a fatality.

6. Serious consideration was given to the initiation of a Special Review because of the potential human and environmental safety concerns identified during the Standard review process. However, it has been determined that the usefulness of the Special Review at this point in time would not justify the time and resources the Agency would have to commit to this procedure for the following reasons:

a. There are significant data lacking. These data are necessary to enable the Agency to complete a risk assessment under the Special Review process and to make a determination regarding the registration status of phorate. Under this Standard, these data are required to be submitted on an expedited basis. Once these data are received, the Agency will initiate an expedited review and evaluation to determine whether the results of these data warrant the initiation of a Special Review.

b. The only benefit to be gained from placing phorate into the Special Review process prior to the submittal and evaluation of the necessary data would be the initiation of a benefits assessment of the currently registered uses of phorate. The Agency is initiating a benefits assessment at this time, so that the assessment will be available in the event a Special Review is deemed necessary. Thus, if a determination is made to initiate the Special Review process for phorate, all pertinent data necessary to complete the process, i.e., to conduct an extensive risk/benefits analysis of the chemical will be available.

E. Criteria For Registration Under This Standard

To be covered by this Standard, products must:

- Contain phorate as the sole active ingredient
- Bear required labeling, and
- Conform to the acute toxicity limits, product composition, and use pattern requirements listed in Section F of this Standard.

The applicant for registration or reregistration of products subject to this Standard must comply with all terms and conditions described in it. That includes making a commitment to fill data gaps on a schedule agreed to by both this Agency and the applicant. Applicants for registration under this Standard must follow the instructions contained in this guidance package and complete and submit the appropriate forms within the time specified.

F. Acceptable Ranges and Limits

1. Product Composition

To be covered under this Standard, technical grade products must contain at least 85 percent phorate as the sole active ingredient. Each manufacturing-use product formulation proposed for registration must be fully described with appropriate certification of limits.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing phorate for acute Toxicity Category I, II, III, or IV, provided that the labeling of these products bears appropriate precautionary statements.

3. Use Patterns

To be registered under this Standard, manufacturing-use products containing phorate may be labeled for formulation only into end-use products for the following use patterns:

- Outdoor, nondomestic use on terrestrial food crops: alfalfa, barley, beans, bermuda grass, corn (field and sweet), cotton, hops, lettuce, peanuts, potato, sorghum, soybeans, sugar beets, sugarcane, tomato and wheat.
- Outdoor, nondomestic use on aquatic food crops: rice
- Outdoor, nondomestic use on terrestrial non-food crops: azalea, birch, boxwood, carnation, chrysanthemum, dahlia, holly and lilies
- Nondomestic greenhouse use on non-food crops: carnations, chrysanthemums, and dahlias

The attached "EPA Index to Registered Pesticides" entry summarizes all currently acceptable uses for all single active ingredient products containing phorate including sites of application, target pests, dosage rates, restrictions and limitations and the method and frequency of application.

End-use products formulated from products registered under this Standard may be granular formulations or liquid formulations.

No new uses of phorate will be considered until the human and environmental concerns raised in this Document are satisfactorily resolved.

G. Required Labeling:

All technical grade, manufacturing-use, and end-use products containing phorate must bear appropriate labeling as specified in 40 CFR 162.10. Other portions of the guidance package contain specific information regarding label requirements. The currently registered manufacturing-use products are in Toxicity Category I and, as such must bear appropriate precautionary labeling as designated in § 162.10 for this high toxicity category including the word Poison (in red) and the skull and crossbones. Statements instructing use of protective clothing, including gloves and goggles, must also appear on all labeling.

1. Manufacturing-Use Products

In addition to the precautionary labeling designated in 40 CFR 162.10 for products in Toxicity Category I, the labels of all manufacturing-use products must contain the following statements:*

- Wear protective clothing, rubber gloves and goggles.
- Wear a pesticide respirator jointly approved by the Mining Enforcement and Safety Administration (formerly the U.S. Bureau of Mines) and by the National Institute for Occupational Safety and Health under provision of 30 CFR Part 11 for organic phosphate protection.

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* It should be noted that the labeling for the currently registered MP already contains the required Category I labeling as well as the protective clothing, rubber gloves, goggles and respirator statements.

- o For formulation into end-use insecticide and/or nematicide products intended for [specify the appropriate use pattern listed in section F.3].
- o The statement, "Do not discharge effluent containing this product directly into lakes, streams, ponds, estuaries, oceans or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency."

2. End-Use Products

In addition to the appropriate Toxicity Category labeling as designated in 40 CFR 162.10, the labels must contain the statements:**

- ° (Granular formulations)

  When applying product, wear protective clothing, gloves and goggles.

- ° (EC formulations)

  When applying product, wear protective clothing, rubber gloves and goggles. Wear a pesticide respirator jointly approved by the Mining Enforcement and Safety Administration (formerly the U.S. Bureau of Mines) and by the National Institute for Occupational Safety and Health under the provisions of 30 CFR Part 11 for organic phosphate protection.

- o Do not reenter treated fields before 24 hours after application. If reentry prior to 24 hours is required, take the same precautions as an applicator of the product including use of protective clothing, gloves and goggles.
- o Not for use or storage in or around the home.

** It should be noted that, with the exception of the recommendation to wear goggles, the first, second and fourth statements, or similar wording already appear on the currently registered labeling.

- Restricted Use Pesticide

  For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicators' certification.

Pending receipt and evaluation of the crop rotation data requested in the accompanying Table A, labeling must include the following restriction: food/feed crops other than those registered for use with phorate may not be planted in phorate-treated soils.

Pursuant to PR Notice 83-2, the general worker protection statements specified in this notice must appear on the labeling of outdoor agricultural use products which are applied to crops whose culture requires hand labor. Such products released for shipment after December 31, 1984, must meet the requirements of this PR Notice.

Additionally, the following statements are required according to uses appearing an the product label.

Greenhouse Uses

- Wear a pesticide respirator jointly approved by the Mining Enforcement and Safety Administration (formerly the U.S. Bureau of Mines) and by the National Institute for Occupational Safety and Health under the provisions of 30 CFR Part 11 for organic phosphate protection.

Terrestrial Crops (Other Than Rice)

- This pesticide is toxic to fish and wildlife. Birds and other wildlife feeding in treated areas may be killed. Do not apply directly to water or wetlands. Runoff and drift from treated areas may be hazardous to aquatic organisms in adjacent sites. Do not contaminate water by cleaning of equipment or disposal of wastes. Cover or incorporate spills.

Use On Rice

- This pesticide is toxic to fish and wildlife. Aquatic organisms may be killed at the recommended application rate. Do not contaminate water by cleaning of equipment or disposal of wastes. Cover and incorporate spills.

H. Tolerance Reassessment

Tolerances ranging from 0.02 to 3.00 ppm have been established for the combined residues of phorate and its cholinesterase-inhibiting metabolites on a variety of raw agricultural food and feed commodities (CFR 180.206), and on the processed feed commodity, dried sugarbeet pulp at 1.0 ppm (21 CFR 561.290). A summary of these tolerances are presented in the table located at the end of this section. Canadian, Mexican and U.S. tolerances are included in this table as well as the maximum residue limits (MRL's) established by the Codex Alimentarius Commission (Codex).

Although plant residues were found to consist almost entirely of oxidation products, the nature and magnitude of the anticholinesterase activity of these individual metabolites were not originally considered in the establishment of existing tolerances. Available studies show certain oxidation products to be more potent cholinesterase inhibitors than the parent compound, and, considering this fact, the actual toxic burden in the diet may be greater than current calculations indicate.

The acceptable daily intake (ADI) for cholinesterase inhibition in man is usually determined on the basis of a no-observed effect level (NOEL) from a chronic feeding study. However, when no chronic feeding data are available for setting the ADI, a provisional acceptable daily intake (PADI) can be established on the basis on a NOEL from a subchronic feeding study. In such cases, of which phorate is one, a 200-fold safety factor is usually applied. A PADI for phorate of .000165 mg/kg was established using a NOEL of 0.66 ppm (0.033 mg/kg) and the maximum permissible intake (MPI) for a 60 kg person is .0099 mg/day.

Toxicological studies are needed to establish acceptable daily intake levels for phorate's more toxic metabolites. The 200-fold safety factor used to establish the PADI may accomodate the uncertainty surrounding greater toxicity and serves to alleviate dietary concerns in the interim between issuance of this Standard and the time the Agency receives and analyzes the metabolite data. The Agency is requiring studies of metabolites utilizing ruminants to determine distribution and characterization of residues in tissues and milk, as well as an animal metabolism study (preferably in the rat) to delineate the pharmokinetic and pharmacodynamic aspects of phorate, particularly the rate of conversion of oxidation metabolites from one to another.

The theoretical maximum residue contribution (TMRC) to the human diet from existing tolerances is 0.1026 mg/day (in 1.5 kg of human diet) and represents 1030.71% of the PADI. However, a reassessment of the current tolerances based on actual constituents of the plant residues is necessary and additional residue data are needed to determine the nature and magnitude of human dietary exposure to phorate's metabolites.

Although the Agency is extremely concerned about the PADI exceedence and considered initiating a Special Review, this action was withheld pending receipt of metabolite toxicity and residue chemistry data with which to evaluate the magnitude of human dietary exposure to phorate and its metabolites. The Agency believes, for several reasons, that the public will be in no "immediate" danger while awaiting exposure assessment data.

The TMRC assumes that 100 percent of the crop for which a tolerance is established is treated with phorate. Phorate's major uses are field corn and potatoes, and the estimated percentage of phorate's use on these crops is low. When adjustments are made for the estimated percentage of crops treated with phorate, the ratio between residue contribution and the PADI is actually much lower that 1030%.

The Agency recognizes that the statistical significance of the Food and Drug Administration's market basket survey is limited, but results from this monitoring can function as an indicator of immediate dietary exposure risks. Monitoring activity for the past several years shows that although present, phorate residues usually do not exceed tolerances, which further alleviates the Agency's immediate concern over phorate's use while collecting data for a tolerance reassessment.

The Agency is requesting data pertinent to the reassessment of current tolerances on an accelerated basis. Until these data are submitted and evaluated, no additional tolerances will be granted.

Additional residue data are required to support tolerances for phorate residues in or on the following commodities: alfalfa (data are required for seed, for which no tolerance currently exists); barley grain and straw, beans and bean vines, corn (grain and sweet corn) and corn forage, cottenseed, hops (processing data only), lettuce, peanuts and peanut hay and vines, potatoes, rice grain, sorghum grain and fodder, soybeans, sugar beet roots and tops, dried sugar beet pulp (21 CFR 561.290), sugarcane (processing data only), tomatoes (processing data only), and wheat grain, fodder, and straw. We are requesting additional data and tolerance proposals for the following commodities for which tolerances are not currently established: barley hay, corn fodder and silage, cotton forage, peanut hulls, sorghum forage, hay, and silage, sugar cane forage, and wheat hay. Feeding and//or grazing restrictions are alternatives to establishing tolerances for residues in or on barley hay, corn foder (popcorn only), cotton forage, sorghum (forage, hay, and silage), sugarcane forage, and wheat hay since these commodities are under the control of the grower. It is critical that additional storage stability data are submitted. It is also necessary that storage conditions and intervals be provided for the samples used to support the currently established tolerances described in this Standard. The limited storage stability data indicate that phorate residues are relatively unstable upon frozen storage in hops; we must know if this is the case with other commodities.

Summary of Present Tolerances for Phorate

Commodity	Canada	Mexico[a]	Codex[b]	U.S.
alfalfa, fresh	-	1.0	-	0.5
alfalfa, hay	-	0.5	1.0	1.0
barley, grain	-	-	0.05	0.1
barley, straw	-	-	-	0.1
beans	0.1	0.1	0.1	0.1
bean, vines	-	-	-	0.5
corn, forage	-	0.5	-	0.5
corn, grain	0.1	-	0.5 (maize-green)	0.1
corn, sweet (K+CWHR)	-	-		0.1
cottonseed	-	0.5	0.05	0.05
eggs	-	-	0.05	0.05
grass, Bermuda, straw	-	-	-	0.5
hops		-	0.1 (dried hops)	0.5
lettuce	0.1	0.1	0.2	0.1
meat, fat and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep*	-	-	0.05	0.05
milk	-	-	0.05 (recommended)	0.02
peanuts	-	0.1	0.05 (without shells)	0.1
peanut, vines	-	- -	-	0.3
peanut, hay	-	0.3	-	0.3
potatoes	0.1	0.5	0.05	0.5
rice	-	0.1	-	0.1
sorghum, fodder	-	-	-	0.1
sorghum, grain	-	0.1	0.05	0.1
soybeans	-	0.1	0.05	0.1
sugar beet, dried pulp	-	-	-	1.0
sugar beet, roots	-	-	0.05	0.3
sugar beet, tops	-	-	1.0	3.0
sugarcane	-	0.1	-	0.1
tomatoes	-	0.1	0.1	0.1
wheat, grain	-	0.05	0.05	0.05
wheat, green fodder	-	1.5	-	1.5
wheat, straw	-	0.05	-	0.05

(a) apparently includes the parent compound only
(b) temporary level

*The Codex level does not include poultry meats nor does it include fat and meat byproducts of any of these animals.

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PHORATE*

TYPE PESTICIDE: Insecticide, Acaricide (also refer to Nematicide entry)

FORMULATIONS: Tech (85%); G (0.15%, 0.166%, 0.2%, 0.4%, 0.5%, 0.67%, 0.8%, 1%, 1.25%, 10%, 15%, 20%); EC (6 lb/gal, 8 lb/gal, 8.7 lb/gal)

GENERAL WARNINGS AND LIMITATIONS: RESTRICTED USE PESTICIDE. Do not plant any crop other than those with registered phorate uses in phorate treated soils.

Bee Caution:
Phorate is toxic to bees exposed to direct treatment. Do not apply while bees are actively visiting the treatment area.

Livestock and Poultry Tolerances:
Meat, fat, meat byproducts of cattle, goats, hogs, horses, poultry, sheep and eggs - 0.05 ppm
Milk - 0.02 ppm

Definition of Terms:
Claims for pest control limited to suppression of population are indicated by parenthesized pest name.

*O,O-diethyl S-[(ethylthio)methyl] phosphorodithioate
Thimet
**covers single active ingredient labeling only

Issued: 5-11-82
Provisional Update: 5-11-84

PHORATE

AGRICULTURAL CROPS

General Warnings and Limitations: Wear protective clothing, gloves, and goggles when applying phorate. Do not reenter treated fields before 24 hours after application. If reentry prior to 24 hours is required, take the same precautions as an applicator of the product including use of protective clothing, gloves, and goggles. Plant injury may occur if granular formulations are placed in direct contact with the seeds of beans, field and sweet corn, lettuce, tomatoes, and sugar beets. Birds and other wildlife feeding in phorate treated areas may be killed. Cover or incorporate spills.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
23001AA	Alfalfa		0.5 ppm (fresh alfalfa) 1 ppm (alfalfa hay) 35 day pregrazing or preharvest interval through 2 pounds per acre for broadcast application.
NASBWC	Alfalfa weevil (larvae	1.5-2 lb/A (10-20% G)	Broadcast application. Apply in the spring when first growth starts. Consult your State Agricultural Extension Service for proper timing of application in your area.
28063AA	Barley (Irrigated)		0.1 ppm (grain, straw) 60 day preharvest interval through 1 pound per acre for broadcast application. Do not allow livestock to graze treated barley.
RACAAA	Aphids	1 lb/A (10-20% G)	Broadcast application. May be applied by aircraft. Irrigate immediately after treatment.

	Site and Pest	Dosages and Formulations	Tolerance, Use, Limitations
28001AA	Beans		0.1 ppm (beans) 0.5 ppm (bean vines) 60 day preharvest or pregrazing interval (for forage) through 1.9 ounces per 1,000 feet of row for banded soil application (at planting). For soil application of granular formulation, do not place in direct contact with seed. Do not make more than 1 application during the growing season to lima and snap beans.
RACAAA RAFAAA CAMARA LAAABA OACAHA MOAAAA	Aphids Leafhoppers Lygus bugs Mites Seedcorn maggot Thrips	0.9-1.4 oz/ 1,000 ft row [minimum 30 inch row spacing] (0.2-20% G)	Soil application at planting (band). Apply evenly in the row to the side of the seed.
A	Mexican bean beetle	0.9-1.9 oz/ 1,000 ft row [minimum 30 inch row spacing] (0.5-20% G)	
22017BA	Bermudagrass		0.5 ppm (straw) 28 day preharvest interval through 1 pound per acre for foliar application. Make only 4 applications per cutting on a maximum of 2 cuttings per year.
AVANA ANAAA AWAAA IOAAAA ABAAA	Banks grass mite Fulgorid planthoppers Mealybugs Thrips Whiteflies	1 lb/A (6 lb/gal EC)	Use limited to AZ and CA. Foliar application to seed crop. Apply in 5 to 10 gallons of water per acre by aircraft or in 25 to 40 gallons of water per acre by ground equipment. For mealybugs, apply when infestations first appear around nodes. For whiteflies, apply when honeydew first appears on plants.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
28006AA	Corn, Field		0.1 ppm (grain) 0.5 ppm (forage) 30 day preharvest or pregrazing interval (for forage) through 1.2 ounces per 1,000 feet of row for foliar application. Do not make more than 1 foliar application during the growing season. Consult your State Agricultural Extension Service for proper timing of application in your area.
RACDKA LAAABA	Corn leaf aphid Mites	1.2 oz/ 1,000 ft row [minimum 30 inch row spacing] (10-20% G)	Use limited to areas other than CA. Foliar application. Apply into the whorls.
IBMCCC	European corn borer (first brood larvae)	1.2 oz/ 1,000 ft row [minimum 30 inch row spacing] (10-20% G)	Use limited to North Central United States. Foliar application. Apply into the whorl just prior to tassel emergence.

Also refer to Corn, Field cluster for additional information.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
28006AA 15005AA	Corn, Field Corn, Sweet		0.1 ppm [grain, sweet corn (kernels plus cob with husk removed)] 0.5 ppm (forage) Banded soil applications (at planting time or at cultivation) through 1.2 ounces per 1,000 feet of row. For soil application of granular formulation, do not place in direct contact with seed.
NAMBHA	Corn rootworms	0.5-1 lb/A (0.2-0.8% G)	Soil application at planting (double band). Apply in the furrow 0.5 to 1 inch above the seeds on each side of the row. Use the higher rate for heavy infestations.
		1.2 oz/ 1,000 ft row [minimum 30 inch row spacing] (0.5-20% G)	Soil application at cultivation (band). Apply in a band at base of plants just ahead of cultivator shovels to cover the granules. Apply in June when pest activity is first observed. Do not make any later applications.
NAMBHA LAAABA	Corn rootworms Mites	0.6-1.2 oz/ 1,000 ft row [minimum 30 inch row spacing] (10-20% G)	Soil application at planting (band). Apply in a 7 inch band over the row behind planter shoe in front of the press wheel. One additional application may be made.
NAKABA	Seedcorn beetle	1.2 oz/ 1,000 ft row [minimum 30 inch row spacing] (10-20% G)	Use limited to IA and IL. Soil application at planting (band). Apply in a 7 inch band over the row behind planter shoe in front of the press wheel. One additional application may be made.
NAVAAA	(Wireworms)	1.2 oz/ 1,000 ft row [minimum 30 inch row spacing] (10-20% G)	Use limited to North Central United States. Soil application at cultivation (band). Apply in a 7 inch band over the row behind planter shoe in front of the press wheel. One additional application may be made.

	Site and Pest	Dosages and Formulations	Tolerance, Use, Limitations
28007AA	Cotton		0.05 ppm (cottonseed) Banded soil application (at planting time) through 1.5 pounds per acre or 1.8 ounces per 1,000 feet of row. The soil temperature, moisture, and tilth should be favorable for good germination. Under adverse conditions, the plant stand may be affected.
RACAAA	Aphids	1.2-1.8 oz/ 1,000 ft row [minimum 36 inch row spacing] (10-20% G)	Soil application at planting (band in furrow). Apply evenly in furrow. For use in areas where an extended period of protection against mites is needed. Use the higher rate for heavier soils.
TBCALA	Black cutworm		
RAFAAA	Leafhoppers		
MAAAGA	Leafminers		
LAAABA	Mites		
MOAAAA	Thrips		
RABAAA	Whiteflies		
		2-2.18 lb/ 150 lb seed [15-20 lb seed/A] (8-8.7 lb/gal EC)	Seed treatment. Wet seed uniformly and dry immediately after treatment. A sticker may be added. Do not use seed for food, feed, or oil purposes.
RACAAA	Aphids	0.367 or 0.6 oz/ 1,000 ft row [minimum 36 inch row spacing] (10-20% G)	Soil application at planting (band in furrow). Apply evenly in furrow. For use in areas where a limited period of protection against early season pests is needed. Use the low rate for hill-dropped cotton.
MAAAGA	Leafminers		
LAAABA	Mites		
MOAAAA	Thrips		
28007AA	Cotton (Irrigated)		0.05 ppm (cottonseed) 60 day preharvest interval through 2.4 ounces per 1,000 feet of row for banded soil application.
LAAABA	Mites	1.8-2.4 oz/ 1,000 ft row [minimum 36 inch row spacing] (10-20% G)	Soil application (band). Apply as a sidedress. For use against spring and early summer mite populations. Apply deep enough to avoid disturbance by subsequent cultivation. Irrigate immediately after application.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
08020AA	Hops		0.5 ppm 42 day preharvest interval through 3 pounds per acre for banded soil applicaton. Do not feed crop refuse to livestock.
RACAAA LAAABA	Aphids Mites	2-3 lb/A (10-20% G)	Soil application (band). Apply in a band over the row after crown growth begins, but before plants are too large. Water in, or hill over.
13020AA	Lettuce		0.1 ppm Banded soil application (at seeding or transplanting) through 0.6 ounce per 1,000 feet or row. For soil application of granular formulation, do not place in direct contact with seed.
[illegible]	Aster leafhopper	0.6 oz/ 1,000 ft row [minimum 18 inch row spacing] (10-20% G)	Use limited to Northeastern United States. Soil application (band). Apply in the fertilizer band on 1 or both sides of the row.
28015AA	Peanuts		0.1 ppm (peanuts) 0.3 ppm (peanut hay and vines) Banded soil application (at pegging) through 2.2 ounces per 1,000 feet of row. Do not graze or feed treated hay or forage to livestock. Plant peanuts when soil temperatures are favorable for establishing good peanut stands.
RAFAAA NAMBMA	Leafhoppers Southern corn rootworm	2.2 oz/ 1,000 ft row [minimum 24 inch row spacing] (10-20% G)	Soil application at pegging (band). Apply in a band over the fruiting zone. Incorporate into the top few inches of soil immediately after application. For control of late season leafhopper infestations.
RAFAAA MOAAAA	Leafhoppers Thrips	1.1 oz/ 1,000 ft row [minimum 24 inch row spacing] (10-20% G)	Soil application at planting (band in furrow). Apply evenly in furrow.

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	Site and Pest	Dosages and Formulations	Tolerance, Use, Limitations
14013AA	Potato		0.5 ppm 90 day preharvest interval through 3.5 ounces per 1,000 feet of row for banded soil application (at planting time or postemergent). Do not make more than 1 application during the growing season.
IRACAAA INAMADC INAMADJ IRAFAAA IMAAAGA IRAXAAA INAVAAA	Aphids Flea beetles (larvae) (Flea beetles (adults)) Leafhoppers Leafminers Psyllids Wireworms (including Southern potato wireworm)	2.2 or 3.5 oz/ 1,000 ft row [minimum 32 inch row spacing] (0.15-20% G)	Soil application at planting (in furrow or double band). Apply evenly in furrow or in a band on each side of the row. Use the low rate for light or sandy soils and high rate for heavy silt, clay loam, or muck soils.
		3.5 oz/1,000 ft row [minimum 32 inch row spacing] (0.166% G)	Postemergent soil application (band). Apply by sidedressing both sides of the row after plants have become established.
NAMCFA	Colorado potato beetle	3.5 oz/ 1,000 ft row [minimum 32 inch row spacing] (15-20% G)	Soil application at planting (in furrow or double band). For early season control in heavy or clay soils. Apply evenly in furrow or in a band on each side of the row.
28072AA	Rice		0.1 ppm 45 day preharvest interval through 2 pounds per acre for broadcast soil application. Do not make more than 1 application during the growing season. Do not permit incidental harvest of crayfish or fish from treated areas. Phorate is toxic to fish and wildlife. Aquatic organisms may be killed at the listed application rate. Cover and incorporate spills.
RAFAAA RAAAEA	Leafhoppers Planthoppers	1-2 lb/A (10-15% G)	Use limited to LA and MS. Broadcast soil application. May be applied by aircraft.

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PHORATE

	Site and Pest	Dosages and Formulations	Tolerance, Use, Limitations
28019AA	Sorghum		0.1 ppm (grain, fodder) 28 day preharvest interval through 1 pound per acre for foliar application. Do not place in direct contact with seed.
LAVANA	Banks grass mite	1 lb/A (10-20% G)	Use limited to the areas other than the Trans Pecos area of TX. Foliar application. May be applied by aircraft. Apply into whorls of plants. Do not make more than 1 postemergent application.
RACDNA	Greenbug	1.2 oz/ 1,000 ft row [minimum 30 inch row spacing] (10-20% G)	Soil application at planting (band or in furrow). Apply in furrow 2 inches to the side and 1 inch below the seed or apply in a 7 inch band over the row ahead of the press wheel. One postemergent application may be made later in the growing season.
		1 lb/A (10-20% G)	Use limited to Western United States. Foliar application. May be applied by aircraft. Apply into whorls of plants. Do not make more than 1 postemergent application.
28023AA	Soybeans		0.1 ppm Banded soil application (at planting time) through 1.9 ounces per 1,000 feet of row. Do not allow livestock to feed on treated foliage. Do not place in direct contact with seed. Crop injury may result when preplant or preemergent applications of metribuzin herbicides or other soil-applied organophosphate pesticides are used in conjunction with phorate.
RAFAAA NAPAFA	Leafhoppers Mexican bean beetle	0.9-1.9 oz/ 1,000 ft row [minimum 30 inch row spacing] (10-20% G)	Soil application at planting (double band). For early season control. Apply in a band on each side of the furrow 2 inches to the side of the seed and 2 inches deep.

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	Site and Pest	Dosages and Formulations	Tolerance, Use, Limitations
28020AA	Sugar Beets		0.3 ppm (roots) 1 ppm (dried pulp for cattle) 3 ppm (tops) 30 day preharvest interval through 1.5 pounds per acre for foliar application. Do not feed treated tops or silage to dairy cattle. Consult your State Agricultural Extension Service for proper timing of application in your area.
RACAAA RAFAAA MAAAGA LAAABA OAXACA	Aphids Leafhoppers Leafminers (including pea leafminer) Mites Sugarbeet root maggot	0.9 oz/ 1,000 ft row [minimum 20 inch row spacing] (0.2-20% G)	Soil application at planting (band, broadcast, or drilling). For band application, apply in a 7 inch band over the row. Do not place in direct contact with seed.
P[illegible]AA [illegible]BA	Aphids Mites	1-1.5 lb/A (10-15% G)	Foliar application. Apply when plants are dry. Use the higher rate for dense foliage. For aphids, may be applied by aircraft when wet soil prohibits ground application.
25003AA	Sugarcane		0.1 ppm Banded soil application (at planting time) through 4 pounds per acre.
NAVAAA	Wireworms	4 lb/A (10-20% G)	Use limited to FL. Soil application at planting (band). Apply in a 10 to 12 inch band directly on the seed pieces and surrounding soil in the furrow immediately before covering.
11005AA	Tomato		0.1 ppm Banded soil application (at planting time) through 2.3 ounces per 1,000 feet of row. Do not place in direct contact with seed.
MAAAGA	Leafminers	2.3 oz/ 1,000 ft row [minimum 38 inch row spacing] (10-20% G)	Use limited to Southeastern United States. Soil application at seeding or transplanting (band). Apply in the fertilizer band on either side of the row.

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	Site and Pest	Dosages and Formulations	Tolerance, Use, Limitations
28065AA	Wheat		0.05 ppm (grain, straw) 1.5 ppm (green fodder) 28 day prefeeding or pregrazing interval through 1 pound per acre for broadcast application (postemergent). 45 day prefeeding or pregrazing interval through 0.25 ounces per 1,000 feet of row for band in furrow soil application (at planting). 70 day preharvest interval for grain through 1 pound per acre for broadcast application (postemergent).
RACAAA	Aphids	1 lb/A (10-20% G)	Use limited to Western United States. Postemergent broadcast application. Apply by aircraft. Apply when pest first appears. Do not apply if a treatment was made at planting. Do not make more than 1 application during the growing season.
RACAAA VABAAA	Aphids Grasshoppers	0.25 oz/ 1,000 ft row [minimum 8 inch row spacing] (1-20% G)	Use limited to Western and North Central United States. Soil application at planting (band in furrow). Do not make any subsequent applications.
OAHAOA	Hessian fly	0.25 oz/ 1,000 ft row [minimum 8 inch row spacing] (1-20% G)	Soil application at planting (band in furrow). Do not make any subsequent applications.

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	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	ORNAMENTALS		
	(Ornamental Plants (herbaceous, woody shrubs, trees and vines))		
	General Warnings and Limitations: Use limited to professional nurserymen and florists in the production of commercially grown ornamentals.		
34022AA 34022DA	Azalea (including nursery stock)		
RACAAA RAFAAA MAAAGA LAAABA	Aphids Leafhoppers Leafminers Mites	8-16 lb/A (10% G)	Broadcast or band soil application. Apply in the spring as a sidedress in the root zone or as a broadcast application over the plants. Use the higher rate for highly organic soils. Water or irrigate immediately after application.
35028AA 35028DA	Birch (including nursery stock)		
A	Birch leafminer	0.3 oz/ 1 in. trunk diameter [measured 2 ft above soil line] (10% G)	Soil application. Apply evenly under tree canopy and incorporate into the soil. For trees growing in clumps. Apply in early spring.
35028DA 34070DA	Birch (nursery stock) Holly (nursery stock)		
MAAAGA	Leafminers	6 lb/A (10% G)	Soil application to nursery stock (band). Apply as a sidedress to both sides of the row.
34031AA 34031DA	Boxwood (including nursery stock)		
RACAAA RAFAAA LAAABA	Aphids Leafhoppers Mites	8-16 lb/A (10% G)	Broadcast or band soil application. Apply in the spring as a sidedress in the root zone or as a broadcast application over the plants. Use the higher rate for highly organic soils. Water or irrigate immediately.
MAAAGA	Leafminers	6 lb/A (10% G)	

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	Site and Pest	Dosages and Formulations	Tolerance, Use, Limitations
31057AA 31057DA	Carnation (including nursery stock)		
RACAAA MOAAAA	Aphids Thrips	5 lb/A or 0.1 lb/ 1,000 sq.ft (10% G)	Broadcast soil application. Apply evenly to the soil surface and water in immediately. Repeat at 28 to 35 day intervals as needed.
31065AA 31065DA	Chrysanthemum (including nursery stock)		
RACAAA RAFAAA LAAABA	Aphids Leafhoppers Mites	20 lb/A or 0.45 lb/ 1,000 sq.ft (10% G)	Broadcast soil application. Apply evenly to the soil surface and water in immediately. Repeat at 28 to 35 day intervals as needed.
31084AA 31084DA	Dahlias (including nursery stock)		
AA RAFAAA LAAABA	Aphids Leafhoppers Mites	16 lb/A or 0.325 lb/ 1,000 sq.ft (10% G)	Broadcast soil application. Apply soon after plants are established. Incorporate evenly into the soil. Soil application (band). Apply as a sidedress application to both sides of the row. Apply soon after the plants are established.
	Holly (nursery stock) See Birch (nursery stock) cluster.		
31131DA	Lilies (bulb production)		
RACAAA	Aphids	8 lb/A (10% G)	Soil application at planting (band in furrow). Apply evenly in the furrow.
		16 lb/A (10% G)	Use limited to Pacific Northwest. Soil application at planting (band in furrow). Apply half of the material beneath or on the bulbs and the remainder added to the dirt layer above the bulbs.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations

(Ornamental and Forest Greenhouse Plants)

General Warnings and Limitations: Wear protective clothing, gloves, and goggles when applying phorate. Wear a pesticide respirator jointly approved by the Mining Enforcement and Safety Administration (formerly the U.S. Bureau of Mines) and by the National Institute for Occupational Safety and Health under the provisions of 30 CFR Part II for organic phosphate protection. Wear clean gloves (rubber or canvas) when handling phorate treated soil for 2 days following application.

31057CA	Carnation		
RACAAA MOAAAA	Aphids Thrips	0.25 lb/ 2,500 sq.ft (10% G)	Broadcast soil application to greenhouse grown plants. Apply evenly to the soil surface and water in immediately. Repeat at 28 to 35 day intervals as needed.
31065CA	Chrysanthemum		
AA A LAAABA	Aphids Leafhoppers Mites	1.13 lb/ 2,500 sq.ft (10% G)	Broadcast soil application to greenhouse grown plants. Apply evenly to the soil surface and water in immediately. Repeat at 28 to 35 day intervals as needed.
31084CA	Dahlias		
RACAAA RAFAAA LAAABA	Aphids Leafhoppers Mites	0.81 lb/ 2,500 sq.ft (10% G)	Broadcast soil application to greenhouse grown plants. Apply soon after plants are established. Incorporate evenly into the soil. Soil application to greenhouse grown plants (band). Apply as a sidedress application to both sides of the row. Apply soon after the plants are established.

AERIAL, MOTHPROOFING AND TANK MIX APPLICATIONS

001500 AAAAAA	Aerial Application		
	—	Refer to AGRICULTURAL CROPS	Barley (irrigated), Bermudagrass, Rice, Sorghum, Sugar Beets, Wheat

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Listing of Registered Pesticide Products by Formulation

85% technical chemical
phorate (057201)
000241-00212   000241-00213   002749-00106

0.15% granular
phorate (057201)
000241-00167

0.166% granular
phorate (057201)
009859-00242

0.2% granular
phorate (057201)
000241-00196   010501-00003

0.4% granular
phorate (057201)
010501-00004

0.5% granular
phorate (057201)
000241-00166   000241-00197   000912-00038   009859-00240

0.67% granular
phorate (057201)
000912-00046

0.8% granular
phorate (057201)
000912-00039

1% granular
phorate (057201)
000241-00226   00241-00227   000241-00228   000912-00069

1.25% granular
phorate (057201)
000912-00068

10% granular
phorate (057201)
000241-00053   002749-00121

15% granular
phorate (057201)
000241-00145   000241-00258   002749-00123   003770-00290

20% granular
phorate (057201)
000241-00257

Listing of Registered Pesticide Products by Formulation (continued)

6 lb/gal emulsifiable concentrate
  phorate (057201) plus xylene (086802)
    000241-00102

8 lb/gal emulsifiable concentrate
  phorate (057201)
    000241-00066

8.7 lb/gal emulsifiable concentrate
  phorate (057201)
    000241-00141

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999999 State Label Registration

WI Reg. No.
    034329-10123

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PHORATE*

TYPE PESTICIDE: Nematicide (also refer to insecticide/acaricide index entry)

FORMULATIONS: G (10%)

GENERAL WARNINGS AND LIMITATIONS: RESTRICTED USE PESTICIDE. Do not use in or near human dwellings, or on house plants, vegetables, flowers, trees and shrubs in or around the home. Do not store in or around the home. When appropriate, use a mask or respirator approved by the National Institute for Occupational Safety and Health under the porvision of 30 CFR part 11. Wear gloves when handling treated soil for a period of one week following application. Do not plant any crop other than those with registered phorate uses in phorate treated soils.

Bee Caution: Phorate is toxic to bees exposed to direct treatment. Do not apply while bees are actively visiting the treatment area.

Agricultural Crop Tolerances: A listing for non-nematicidal uses follows: 3 ppm in or on sugar beet tops. 1.5 ppm in or on wheat (green fodder). 1.0 ppm in or on alfalfa hay and dried sugarbeet pulp. 0.5 ppm in or on alfalfa (fresh), bean vines, bermudagrass straw, corn forage, hops (dried) and potatoes. 0.3 ppm in or on peanut vines and hay and sugarbeet roots. 0.1 ppm in or on barley grain, barley straw, beans, corn grain, sweet corn (kernel plus cob with husk removed), lettuce, peanuts, rice, sorghum grain, sorghum fodder, soybeans, sugarcane and tomatoes. 0.05 ppm in or on cottonseed, wheat grain and wheat straw.

Livestock and Poultry Tolerances: 0.02 ppm in milk. 0.05 ppm in meat, fat and meat byproducts of cattle, goats, hogs, horses, poultry and sheep, and in eggs.

Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitation	
ORNAMENTALS			
Ornamental Plants (herbaceous plants and bulbs, woody shrubs, trees and vines)			
General Warnings and Limitations: Do not grow edible crops on soil treated with phorate at the rate indicated for ornamentals.			
Azaleas			/34151AA
Stylet nematodes Meadow nematodes	8.0-16.0 lb/A (10% G)	Soil application. Apply in the spring as a side dress in the root zone area, or as a broadcast treatment over the plants. The heavier rate is necessary on soils high in organic matter. Water or irrigate immediately following treatment.	NELBAAA NEJBBAA

*O,O-Dimethyl S-[(ethylthio) methyl] phosphorodithioate
Thimet
Rampart

Site and Pest	Dosages and Formulation(s)	Tolerance, Use, and Limitations	
ORNAMENTALS (continued)			
Boxwood	8.0-16.0 lb/A (10% G)		/34031AA
Meadow nematodes Pin nematodes		Soil application. Apply in the spring as a side dress in the root zone area, or as a broadcast treatment over the plants. The heavier rate is necessary on soils high in organic matter. Water or irrigate immediately following treatment.	NEJBBAA NEIBBAA
Lilies			/31131AA
Root Lesion Nematodes	16.0 lb/A (10% G)	Use limited to Pacific Northwest. Soil Application. Apply the granules evenly in the furrow at planting time, placing one-half the material beneath or on the bulbs and the remainder added to the soil layer above the bulbs.	NEJBBAA

PHORATE

Listing of Registered Pesticide Products by Formulation (Nematicides)

10% granular
  phorate (057201)
    002749-00121

TABLE A
GENERIC DATA REQUIREMENTS FOR PHORATE

§158.120-PRODUCT CHEMISTRY

Guideline Citation and Name of Test	Test Substance1/	Guideline Status 2/	Are Data Required4/ Yes	No
Product Identity:				
61-1 - Identity of Ingredients	MP	R	☒	☐
61-2 - Statement of Composition	MP	R	☒	☐
61-3 - Discussion of Formation of Ingredients	MP	R	☒	☐
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis	MP	CR	☒	☐
62-2 - Certification of Limits	MP	R	☒	☐
62-3 - Analytical Methods for Enforcement of Limits	MP	R	☒	☐
Physical and Chemical Characteristics				
63-2 - Color	MP	R	☒	☐
63-3 - Physical State	MP	R	☒	☐
63-4 - Odor	MP	R	☒	☐

: :

TABLE A
GENERIC DATA REQUIREMENTS FOR PHORATE

§158.120-PRODUCT CHEMISTRY

Guideline Citation and Name of Test	Test Substance[1]	Guideline Status [2]	Are Data Required[4] Yes	No
Physical and Chemical Characterisics (continued)				
63-5 - Melting Point	TGAI	R	☐	☒[3]
63-6 - Boiling Point	TGAI	R	☒	☐
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	R	☒	☐
63-8 - Solubility	TGAI or PAI	R	☒	☐
63-9 - Vapor Pressure	PAI	R	☒	☐
63-10- Dissociation constant	PAI	R	☒	☐
63-11- Octanol/water partition coefficient	PAI	R	☒	☐
63-12- pH	TGAI	R	☒	☐
63-13- Stability	TGAI	R	☒	☐
63-20- Corrosion Characteristics	TGAI	R	☒	☐
Other Requirements:				
6 - 1 - Submittal of samples	Choice	CR	☐	☒

: :

DATA REQUIREMENT FOOTNOTES:

[1] Test substance: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient.
[2] R = Required under the guidelines; CR = Conditionally required.
[3] Not required because the technical material is liquid at room temperature.
[4] Data must be submitted no later than 6 months from date of this Standard.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHORATE

Data Requirement	Composition[A/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)[B/]
§158.125 Residue Chemistry				
171-4 - Nature of Residue (Metabolism)				
- Plants	PAIRA	partially	GS0103001 thru - 9	Yes[1/]
- Livestock	PAIRA and plant metabolites	partially	GS0103003;GS0103010	Yes[2/]
- Residue Analytical Method				
- Plant residues	Pure Analytical Standard and metabolities	Yes	GS0103011 thru - 14;* GS0103017 thru - 39;* GS0103043*;GS0103044*	No[3/]
- Animal residue	Pure Analytical Standard and metabolities	Yes	GS0103015*;GS0103016*;GS0103040* GS0103041*;GS0103042*;GS0103045*	No[3/]
171-4 - Storage Stability Data	PAI	partially	GS0103046	Yes[4/]
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use				
° Root and Tuber Vegetable Group				
- Potatoes	TEP	Partially	GS0103047	Yes[5/]

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*Data submitted by American Cyanamid. These data may be compensable.

TABLE A

GENERIC DATA REQUIREMENTS FOR PHORATE

Data Requirement	Composition[A/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)[B/]
§158.125 Residue Chemistry (continued)				
- Sugar beets	TEP	Partially	GS0103048;GS0103049;GS0103050 GS0103051;GS0103052	Yes[6/]
Dried sugar beet pulp	EP	Partially	GS0103050	Yes[6/]
° Leaves of Root and Tuber Vegetable Groups				
- Sugar beet tops	TEP	Partially	GS0103051 thru - 57	Yes[7/]
° Leafy Vegetables Group (except Brassica)				
- lettuce	TEP	Partially	GS0103058	Yes[8/]
° Legume Vegetables (Succulent or Dried) Group				
- Beans	TEP	Partially	GS0103059	Yes[9/]
- Soybeans	TEP	Partially	GS0103060	Yes[10]
° Foliage of Legume Vegetables Group				
- Bean vines	TEP	No		Yes[11]
° Fruiting Vegetables				
- Tomatoes	TEP	Partially	GS0103061;GS0103062 GS0103063	Yes[12/]

TABLE A
GENERIC DATA REQUIREMENTS FOR PHORATE

Data Requirement	Composition[A]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)[B]
§158.125 Residue Chemistry (continued)				
° Cereal Grains Group				
- Barley grain	TEP	Partially	GS0103064	Yes[13]
- Corn (fresh and grain)	TEP	Partially	GS0103065;GS0103066 GS0103067	Yes[14]
- Rice grain	TEP	Partially	GS0103068;GS0103069	Yes[15]
- Sorghum grain	TEP	Partially	GS0103070;GS0103071	Yes[16]
- Wheat grain	TEP	Partially	GS0103072;GS0103073 GS0103074;GS0103075	Yes[17]
Forage, Fodder & Straw of Cereal Grain Group				
- Barley Straw	TEP	Partially	GS0103076;GS0103077	Yes[18]
- Corn Forage	TEP	Partially	GS0103065;GS0103078 GS0103079;GS0103080	Yes[19]
- Rice straw	TEP	Partially	GS0103068;GS0103081	Yes[20]
- Sorghum Fodder	TEP	Partially	GS0103082;GS0103070	Yes[21]
- Wheat (fodder and straw)	TEP	Partially	GS0103072;GS0103073 GS0103074;GS0103083	Yes[22]
° Grass Forage, Fodder and Hay Group				
- Bermuda grass	TEP	Yes*	GS0103084	No[23]

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*Data submitted by American Cyanamid. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHORATE

Data Requirement	Composition[A]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)[B]
§158.125 Residue Chemistry (continued)				
° Non-Grass Animal Feeds Group				
- Alfalfa	TEP	Partially	GS0103085;GS0103086 GS0103087	Yes[24]
° Miscellaneous Crops				
- Cotton seed	TEP	Partially	GS0103088;GS0103089; GS0103090;GS0103091; GS0103092	Yes[25]
- Hops	TEP	Partially	GS0103093;GS0103094 GS0103095	Yes[26]
- Peanuts	TEP	Partially	GS0103096;GS013097 GS010398	Yes[27]
- Sugarcane	TEP	Partially	GS0103101	Yes[28]
- potable Water	EP	Not Applicable	-	-
- Fish	EP	Not Applicable	-	-
- Irrigated Crops	EP	Not Applicable	-	-
-- Field trials	EP			
-- Processed Food/Feed	EP			
- Food Handling	EP	Not Applicable	-	-
- Meat/milk/poultry/eggs	TGAI or plant metabolites	Partially	GS0103099;GS0103100	Yes[29]

[A] Composition: TGAI = Technical grade of the active ingredient; PAI = pure active ingredeint; PAIRA = Pure active ingredient, radiolabelled. TEP = Typical end-use product; EP = end-use product.

[B] Data must be submitted no later than 18 months from date of this Standard except for the metabolism data which are due within 1 year from date of this Standard.

§158.125 Residue Chemistry Footnotes

1. The quantification of the individual oxidation products of phorate contained in the residue in or on raw agricultural commodities for which tolerances have been established as a result of the maximum recommended use of phorate must be submitted.

2. Presently, the metabolism of phorate [O,O-diethyl S-[(ethylthio)methyl] phosphorodithioate] in animals is not adequately understood. The available ruminant study did not include identification of residues in tissues (muscle, liver, kidney, and fat) or in milk. The following additional data are required:

    - Metabolism studies utilizing ruminants. Animals must be dosed with [^{32}p]phorate, [^{32}p]phorate sulfoxide, and [^{32}p]phorate sulfone, and distribution and characterization of residues must be determined in tissues and milk. If ruminant metabolism is found to differ significantly from that in rats, then swine metabolism data will also be required.

3. Collectively, the studies fulfill the data requirement. At this moment, no additional methodology is required: however, there is a reasonable expectation that in the effort to satisfy the indicated data gaps, especially those involved with the quantitation of the individual metabolites in the tolerance expression, that additional methodology will be needed.

4. The storage stability of phorate residues in or on animal and plant samples is not adequately understood. The following additional data are required:

    - The stability of phorate, phorate sulfoxide and phorate sulfone must be determined in or on representative crops (such as corn grain and forage, cottonseed, potatoes, and soybeans) and animal products (meat, milk, and eggs). Samples must be stored at subfreezing temperatures.

    - Information must be provide as to the condition and length of storage of samples collected for commodities (animal and plant) presented in this standard. Very limited information was provided in regard to this subject.

5. The available data do not support the established tolerance for the combined residues of phorate and its cholinesterase-inhibiting metabolites in or on potatoes because a potato processing study was not submitted. The following data are required:

    - Residues in dried potoes and potato chips and granules must be determined after processing field-treated potatoes containing 0.5 ppm combined residues of phorate and its cholinesterase-inhibiting metabolites.

6. The available data are not adequate to support the established tolerance for the combined residues of phorate and its cholinesterase-inhibiting metabolites in or on sugar beets or dried sugar beet pulp, because an aerial application study was not submitted, the submitted studies lack adequate geographic representation, and processing studies are inadequate. The following data are required:

   - Aerial application studies on established sugar beets at 1.5 lb ai/A (a representative G formulation) must be performed in CA, ID, and MN, which produce 25, 14, and 15%, respectively, of the sugar beet crop.

   - Field trials that include ground-applied soil and foliar treatments at 1.5 lb ai/A (representative G) in one or more of the following states: MN, ND, NE, or MI.

   - Determination of residues in pulp, molasses, and refined sugar made from sugar beets that were field-treated and which contain residues at or near the tolerance level.

7. The submitted studies do not include a test of aerial application methods and lack adequate geographic representation. The following data are required:

   - Aerial application studies on established sugar beets using 1.5 lb ai/A (a representative G formulation) conducted in CA, ID, and MN.

   - Field trials that include at-plant and foliar applications at 1.5 lb ai/A (representative G) in one or more of the following states: MN, ND, NE, or MI.

8. The available data are not sufficient to assess the adequacy of the established tolerance and label directions. The following additional data are required:

   - Residue data from tests conducted in northeastern states using the 10% G, 15% G, or 20% G at 1.09 lb. ai/A as a soil application on both sides of the row both at seeding or transplanting. Both leaf and head lettuce must be treated.

9. The available data are not sufficient to assess the adequacy of the established tolerance and label directions. The following additional data are required:

   - Residue data involving phorate residues in or on beans (succulent and dried) following a soil application at-planting of a representative G formulation at 2.07 lb ai/A from tests conducts in central (ID, MI, ND, NE, or WI) and western (CA, OR, or WA) locations.

10. The available data are insufficient to assess the adequacy of the established tolerance and label directions. The following additional data are required:

- Residue data from tests conducted in western, central, and midwestern locations involving the application of the 10% G, 15% G, or 20% G at 2.07 lb ai/A.

- Residue data for meal, hulls, soapstock, and oil processed from field-treated soybeans containing detectable residues; treatement at exaggerated rates may be necessary to obtain detectable residues. If residues are found to concentrate in any of these processed products (oil, meal, soapstock) appropriate food/feed additive tolerances must be proposed.

11. The available data are not sufficient to assess the adequacy of the established tolerance and label directions. The following additional data are required:

- Residue data involving phorate residues in or on bean vines and hay following a soil application at-planting of a representative G formulation at 2.07 lb ai/A from tests conducted in eastern, central, and western locations. Based on the requested data, a tolerance for phorate residues in or on bean hay should be proposed.

12. The available data are not sufficient to fully assess the adequacy of the established tolerance and label directions. The following additional data are required

- Residue data involving phorate residues in or on the processed products of tomatoes (pomace, puree, catsup, and juice) processed from field-treated tomatoes at the maximum recommended use.

13. The available data do not support the established tolerance for the combined residues of phorate and its cholinesterase-inhibiting metabolites in or on barley grain. The following data are required:

- Residue analyses on barley grain samples taken 60 days after foliar treatment at 1 lb ai/A (G formulation, broadcast) using both aerial and ground equipment in each of the following states: CA, ND, and WA. The test plots must be irrigated immediately after treatment.

Residue data for barley germ and representative milled barley products will not be specifically required because the requested data for processed products of wheat will be translated to barley.

14. The available data do not fully support the tolerance for phorate residues in or on field corn grain and sweet corn (kernels plus cobs with husks removed). The following additional data are required:

- Residue data reflecting an at-planting soil application of one of the G formulations at 1.3 lb ai/A followed by an at-cultivation soil application (made when corn is 4-6 inches tall) at 1.3 lb ai/A. Data must include tests for residues both in field corn grain and sweet corn (kernels plus cobs with husks removed). Field corn tests should be conducted in Corn Belt states (IL, IN, IA, MN, NE, and OH); sweet corn tests should be conducted in FL, MN, NY, and OR [representing >90% of processed and >63% of fresh market sweet corn production areas in the U.S. (Agricultural Statistics, 1981, p. 170)].

- Residue data (field corn grain only) reflecting an at-planting soil application of one of the G formulations at 1.3 lb ai/A followed by a foliar application at 1.3 lb ai/A made 30 days prior to harvest; tests should be conducted in Corn Belt states (IL, IN, IA, MN, NE, and OH). Also, residue data (field corn grain only) reflecting an at-cultivation soil application (made when plants are 4-6 inches tall) of one of the G formulations at 1.3 lb ai/A followed by a foliar application at 1.3 lb ai/A made 30 days prior to harvest; tests should be conducted in north central states (IA, MN, and NE).

- Residue data (field corn grain only) reflecting an at-planting soil application of the current registered liquid formulation (6 lb. phorate/gal.) at the current registered application rate (1.6 fl.oz. product per 1,000 ft. of row); tests should be conducted in Corn Belt States (IL, IN, LA, MN, NE and OH).

- Residue data reflecting residues in the processed products of field corn grain (crude and refined oil) and of sweet corn (cannery waste). If residues of phorate and/or its cholinesterase-inhibiting metabolites are found to concentrate in any of these processed products, appropriate food/feed additive tolerances must be proposed.

15. The available data do not support the established tolerance for phorate residues in or on rice. The following data are required:

    - Residue data reflecting a single broadcast aerial application of one of the G formulations at 2 lb ai/A made 45 days prior to harvest; tests should be conducted in either MS or LA.

    - Residue data for milled rice products, rice hulls and polished rice, obtained from processing samples of field-treated rice grain containing detectable residues (exaggerated rates may be necessary).

16. The available data do not fully support the tolerance for phorate residues in or on sorghum grain. The following additional data are required:

    - Residue data reflecting an at-planting soil application of one of the G formulations at 1.3 lb ai/A followed by a foliar application (both aerial and ground applied) at 1 lb ai/A made 28 days prior to harvest. Tests should be conducted in KS and TX [representing >93% of U.S. sorghum grain production area (Agricultural Statistics, 1981. p. 52)].

Residue data will not be specifically required for the processed products of sorghum grain (flour and milled products) because the requested data for residues in processed products of corn and wheat will be tranlated to sorghum products. If residues of phorate and/or its cholinesterase-inhibiting metabolites are found to concentrate in any of the processed products of wheat or corn, then appropriate food additive tolerances must be proposed for sorghum products.

17. The available data do not support the established tolerance for phorate residues in or on wheat grain. The following data are required:

    - Results of field trials employing single aerial applications at 1 lb ai/A (10-20% G formulation) as a postemergence treatment in one or more of the following states: CA, OR, WA, CO, ID, or MT.

    - A study examining the residues in milled products of wheat obtained from field-treated grain containing detectable residues (treatment at an exaggerated rate may be necessary).

18. The available data do not support the established tolerance for the combined residues of phorate and its cholinesterase-inhibiting metabolites in or on barley straw. In addition, a tolerance must be established for barley hay; data requested for wheat hay will be translated to barley hay. Alternatively, a feeding restriction could be proposed for barley hay. The following data are required:

    - Residue data from barley straw samples taken 60 days after foliar treatment at 1 lb ai/A (G formulation, broadcast) using both aerial and ground equipment in each of the following states: CA, ND, and WA. The test plots must be irrigated immediately after treatment.

    A barley forage tolerance is not required due to the grazing restriction which is now in effect.

19. The available data do not fully support the tolerance for phorate residues in or on corn forage. The following additional data are required:

    - Residue data reflecting an at-planting soil application of one of the G formulations at 1.3 lb ai/A followed by an at-cultivation soil application (when corn is 4-6 inches tall) at 1.3 lb ai/A; data are required for sweet corn only. Tests should be conducted in FL and OR.

    The adequacy of the tolerance cannot be assessed at this time due to the absence of the data requested above. Although the data support registered uses on field corn, additional data are needed to obtain full geographic representation for sweet corn (see data gap above).

    The 30-day pregrazing restriction for foliar applications should be extended to at-planting and at-cultivation applications. Also, since field corn silage and fodder are raw agricultural commodities, appropriate tolerances for residues in or on these commodities must be established. We conclude that the available data for corn forage are translatable to silage and fodder and that tolerances of 0.5 ppm for combined residues of phorate and its cholinesterase-inhibibiting metabolites in or on these commodities will be adequate.

20. The available data are insufficient to allow us to recommend a specific tolerance in or on rice straw. The following data are required to allow us to make such a recommendation:

    ° Studies, in LA and MS, of residues remaining on rice straw 45 days after treatment with 2 lbs ai/A (10% or 15% G) broadcast soil applications using both aerial and ground equipment. Alternatively, a feeding restriction for phorate-treated rice straw may be proposed.

21. The available data do not support the established tolerance for phorate residue in or on sorghum fodder; residues exceeded the established tolerance at the established 28-day PHI. In addition, the registrant did not specify whether foliar treatments were aerial- or ground-applied. Also, no residue data were submitted for sorghum hay. The following additional data are required:

    ° Residue data reflecting an at-planting soil application of one of the G formulations at 1.3 lb ai/A followed by a foliar application (both aerial- and ground-applied) at 1 lb ai/A made 28 days prior to harvest; data are required both for sorghum fodder and hay. Tests should be conducted in KS and TX [representing >70% of U.S. sorghum silage production areas (Agricultural Statistics, 1981, p. 52)]. A tolerance for combined residues of phorate and its cholinesterase-inhibiting metabolites in or on sorghum hay must be proposed; alternatively a sorghum hay feeding restriction may be imposed.

    The available data indicate that the tolerance for sorghum fodder should be increased; however, a final recommendation for s specific tolerance will not be possible until the data requested above have been submitted.

    Sorghum forage and silage are additional raw agricultural commodities for which no phorate residue tolerances have been established. Sorghum fodder data are translatable to forage and silage; therefore, the tolerance which will be recommended for fodder should also be established for forage and silage. In addition, an appropriate pregrazing interval must be established for sorghum forage.

22. The available data do not support the established tolerances for phorate residues in or on wheat fodder and straw. The following data are required:

    ° Wheat straw residue data from plots treated, in separate trials, with a G formulation at 1 lb ai/A as both an at-plant soil (ground-applied) and foliar application (aerially-applied) in each of the following states: WA, TX, and ND.

    A tolerance should be established for wheat hay. The following data will be required:

- A study showing the effects of drying whole, green wheat plants, field-treated at 1 lb ai/A, on residues in the subsequent hay. Alternatively, a wheat hay feeding restriction could be imposed.

23. Since fresh bermuda grass is a raw agricultural commodity, a grazing restriciton must be imposed. The submitted data are adequate to support established tolerance for Bermuda grass straw.

24. The available data are adequate to support the established tolerances for phorate residues in or on alfalfa (fresh) and alfalfa hay which may result from use of the registered formulations in accordance with the established label directions at the maximum registered rate. However, since alfalfa seed is a raw agricultural commodity, the following data are required:

    - Data reflecting residues in or on alfalfa seed following applications made at the maximum registered rate (2 lb ai/A). A tolerance may be needed if residues in the seed exceed those in the hay (1 ppm).

25. The available data do not fully support the established tolerance for the combined residues of phorate and its cholinesterase-inhibiting metabolites in or on cottonseed because insufficient data are available pertaining to residues in forage. Since cotton forage is a feed item for dairy and beef cattle, a tolerance is necessary and additional data are required (outlined below). Furthermore, data pertaining to residues resulting from phorate-treated cottonseed do not reflect the maximum registered rate. Finally, the submitted processing studies are of little value because preprocessing residue values were not provided. The following additional data are required:

    - Residue data on cotton foliage and cottonseed at intervals up to 60 days reflecting treated cottonseed with 8 or 8.7 lb/gallon EC at 2.18 lb ai/150 lb of seed after which 20 lb of the treated seed are planted per acre (0.3 lb ai/Acre) and in addition reflecting a sidedress application of 2.2 lbs ai/Acre. Tests should be conducted in CA, MS and TX which produce 28%, 10% and 30% respectively of the annual crop (Agricultural Statistics, 1981, p. 114). Based on these data, a cotton forage tolerance and an appropriate pregrazing interval must be proposed. Alternatively, a label restriction against feeding or grazing of cotton forage may be proposed.

    - Processing data reflecting combined residues of phorate and its cholinesterase-inhibiting metabolites in hulls, meal, soapstock, and oil (crude and refined) from field-treated cottonseed containing detectable phorate residues (exaggerated rates may be necessary to obtain detectable residues).

26. Residue data are needed for dried and spent hops processed from fresh hops.

27. The available data do not support the established tolerances for combined residues of phorate and its cholinesterase-inhibiting metabolites in or on peanuts and peanut vines and hay, because they do not reflect the

maximum application rate of the registered formulations. Also, a processing study utilizing samples containing field-treated detectable residues was not submitted. The following additional data are required:

- Tests conducted in GA, NC, and TX (~ 98% of all peanuts are produced in or adjacent to these states) with one of the G formulations re-flecting at-planting (1.5 lb ai/A) and at-pegging (3 lb ai/A) soil applications resulting in a total of 4.5 lb ai/A applied. Total phorate residues must be determined in or on nutmeats, hulls, vines and hay. Since peanut hulls constitute a raw agricultural commodity not under the control of the grower, an additional tolerance for hulls must be proposed.

- Field-treated nutmeats containing detectable residues of phorate and/or its cholinesterase-inhibiting metabolites must be processed to determine residues in meal, soapstock, and oil (crude and refined); if residues are found to concentrate in any of these processed products, appropriate food/feed additive tolerances must be proposed.

28. The available data do not fully support the established tolerance for combined residues of phorate and its cholinesterase-inhibiting metabolites in or on sugarcane because a processing study utilizing field-treated samples containing detectable residues was not submitted. Also, no data were submitted pertaining to phorate residues in or on sugarcane forage. The following data are required:

    - Residue data for sugarecane forage (grown in FL) at various intervals up to 15 months after an at-plant soil application of one of the G formulations at 4 lb ai/A; a tolerance and pregrazing interval must be proposed. Alternatively, grazing and feeding restrictions may be imposed.

29. The metabolism of phorate in animals is not adequately understood due to lack of pertinent data on this topic. Should the metabolites of concern differ from those currently sought and reported here, additional data will be required. Presently, the available data do not support the established tolerances for phorate residues (including its cholinesterase-inhibiting metabolites) in the meat, fat, and meat by-products of cattle, goats, hogs, horses, poultry, and sheep and in eggs due to the lack of the indicated animal metabolism and feed item residue data.

    Presently, the available data support the established tolerances for phorate residues (including its cholinesterase-inhibiting metabolites) in milk and are sufficient to assess the adequacy of the tolerance. Should the metabolites of concern differ from those currently sought and reported here, additional data will be required.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHORATE

Data Requirement	Composition[1/]	Use [2/] Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)[3/]
§158.130 Environmental Fate					
DEGRADATION STUDIES-LAB:					
161-1 - Hydrolysis	TGAI or PAIRA	A,B,C,F	No	-	Yes
Photodegradation					
161-2 - In water	TGAI or PAIRA	A,B,C	No	-	Yes
161-3 - On soil	TGAI or PAIRA	A,B	No	-	Yes
161-4 - In air	TGAI or PAIRA	A,B,F	No	-	Yes
METABOLISM STUDIES-:LAB:					
162-1 - Aerobic Soil	TGAI or PAIRA	A,B	No	-	Yes
162-2 - Anaerobic Soil	TGAI or PAIRA	A,B	No	-	Yes[4/]
162-3 - Anaerobic Aquatic	TGAI or PAIRA	C	No	-	Yes
162-4 - Aerobic Aquatic	TGAI or PAIRA	C	No	-	Yes
MOBILITY STUDIES:					
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B,C,F	Partial	GS0103107	Yes[5/]
163-2 - Volatility (Lab)	TEP	A,B,F	No	-	Yes
163-3 - Volatility (Field)	TEP	A,B,F	No	-	Yes[6/]
DISSIPATION STUDIES-FIELD:					
164-1 - Soil	TEP	A,B	No	-	Yes[9/][11/]
164-2 - Aquatic (Sediment)	TEP	C	No	-	Yes[9/]

TABLE A
GENERIC DATA REQUIREMENTS FOR PHORATE

Data Requirement	Composition[1]	Use[2] Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)[3]
§158.130 Environmental Fate (continued)					
DISSIPATION STUDIES-FIELD: (continued)					
164-3 - Forestry	TEP	-	No	-	No[10]
164-4 - Combination and Tank Mixes	TEP	-	No	-	No[7]
164-5 - Soil, Long-term	TEP	A,B,C	No	-	Yes[8]
ACCUMULATION STUDIES:					
165-1 - Rotational Crops (Confined)	PAIRA	A,B,C	No	-	Yes
165-2 - Rotational Crops (Field)	TEP	A,B,C	No	-	Yes
165-3 - Irrigated Crops	TEP	C	No	-	Yes
165-4 - In Fish	TGAI or PAIRA	A,B,C	No	-	Yes
165-5 - In Aquatic Non-Target Organisms	TEP	C	No	-	Yes
Subpart K Re-entry					
132-2 - Foliar Dissipation	TEP	A,B,C	No	-	Yes
132-2 - Soil Dissipation	TEP	A,B,C	No	-	Yes
133-3 - Dermal Exposure	TEP	A,B,C	No	-	Yes
133-4 - Inhalation Exposure	TEP	A,B,C	No	-	Yes

TABLE A
GENERIC DATA REQUIREMENTS FOR PHORATE

§158.130 Environmental Fate
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ Data must be submitted no later than 3 years from date of this Standard, except §161-1, -2, -3; 133-3, -4, and 163-1, which are due within 6 months; and 162-1, -2, -3, -4 and 164-1, -2 which are due within 2 years from date of this Standard.

4/ Data from an anerobic soil metabolism study need not be submitted if data from the anaerobic aquatic metabolism study (162.3) have been submitted.

5/ Felsot and Dahm (1979) partially fulfill this data requirement by providing information on the mobility of phorate (unaged) in sandy loam, loamy sand, silt loam, loam and peat soils. A study is needed which provides data on the mobility of phorate aged in a sandy loam soil and adsorption/desorption data for phorate on one aquatic sediment.

6/ May be required, depending on results from 163-2 (Lab volatility).

7/ Pursuant to PR Notice 82-1, entitled "Revised Policy on Label Claims for Tank Mixing" (January 12, 1982), these data are only required on a case-by-case basis.

8/ May be required, depending on results from 162-1 or 164-1 and 164-2(b)(1).

9/ Must sample beyond leaching depth for phorate and toxic degradates.

10/ Currently, there are no forest uses registered for phorate.

11/ The terrestrial field dissipation study must be conducted for potatoes on sandy soil in Long Island, New York. This is required because a ground water leaching simulation (PRZM model) in Long Island indicates phorate has a potential for leaching.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHORATE

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)[3]
§158.135 Toxicology					
ACUTE TESTING:					
81-1 - Acute Oral Toxicity - Rat	TGAI	ABCF	YES	05014313	NO
81-2 - Acute Dermal Toxicity	TGAI	ABCF	YES	05014313	NO
81-3 - Acute Inhalation Toxicity - Rat	TGAI	ABCF	YES	05014313	NO
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	ABCF	NO		YES
SUBACUTE TESTING:					
82-1 - 90-Day Feeding - Rodent, Non-rodent	TGAI	A,C	Partially	0056714*	NO[4]
82-2 - 21-Day Dermal	TGAI	ABCF	NO	-	YES[5]
82-3 - 90-Day Dermal	TGAI	ABCF	NO	-	NO[17]
82-4 - 90-Day Inhalation - Rat	TGAI	ABCF	NO	-	YES[6]
82-5 - 90-Day Neurotoxicity Hen/Mammal	TGAI	ABCF	NO	-	YES[7]
CHRONIC TESTING:					
83-1 - Chronic Toxicity - 2 species: Rodent and Non-rodent	TGAI	A,C	Partially	GS0103108*	YES[8]
- 6-month Toxicity- 2 species: rat and dog	Oxidation metabolites	A,C	NO	-	YES[14]

TABLE A
GENERIC DATA REQUIREMENTS FOR PHORATE

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)[3]
§158.135 Toxicology (continued)					
CHRONIC TESTING: (continued)					
83-2 - Oncogenicity Study -2 species: Rat and Mouse preferred	TGAI	A,C	YES	GS0103108* GS0103109*	NO[16]
83-3 - Teratogenicity - 2 species	TGAI	ABCF	Partially	GS0103110*	YES[9]
83-4 - Reproduction, 2-generation	TGAI	ABCF	YES	00092853*	NO
MUTAGENICITY TESTING:					
84-2 - Gene Mutation	TGAI	ABCF	Partially	05009139	YES[10]
84-2 - Chromosomal Aberration	TGAI	ABCF	Partially	05009139	YES[11]
84-2 - Other Mechanisms of Mutagenicity	TGAI	ABCF	NO		YES[12]
SPECIAL TESTING					
85-1 - General Metabolism	PAI or PAIRA	A,C	Partially	00034931 00092908 00092877	YES[13]
85-2 - Domestic Animal Safety	Choice	A,B	YES	00092978 00013487	NO[16]
Product Integrity Studies	TEP (Granular)	ABCF	NO	-	YES[15]

TABLE A
GENERIC DATA REQUIREMENTS FOR PHORATE

§158/135 Toxicology
(continued)

1/ Composition: PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabelled; Choice = Choice of several test substances determined on a case-by-case basis. TEP = typical end-use product.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ Data must be submitted no later than 3 years from date of this Standard except for the general metabolism (85-1), mutagenicity (84-2), and the 6-month feeding study on the metabolites (83-1) which are due within one year from date of the Standard.

4/ A study in the rat is available. Since a chronic study in a non-rodent is being required under this Standard, a subchronic (90-day) feeding study in a non-rodent would not be needed.

5/ Contingent upon results of the product integrity studies, as required under toxicology special testing, and if repeated exposure is shown to be possible.

6/ Only if product integrity studies, as required under toxicology special testing, indicate that respirable dust is generated during shipping and handling of the granular formulations.

7/ Contingent upon the results of the acute delayed neurotoxicity.

8/ Testing required in a non-rodent species. Though the available chronic rat feeding study is classified as supplementary, re-testing of the rat may not be necessary since the current study indicates that cholinesterase is the primary target for the action of Phorate, and determination of the "no-observed effect level" for cholinesterase inhibition can be achieved through an adequate subchronic feeding study on the identified metabolites.

9/ Testing is required in a second species (other than the rat). This study has been completed and is currently under review by the Agency.

10/ *In vitro* gene mutation in mammalian cells testing is required.

11/ Sister chromatid exchange testing is required.

12/ Contingent upon the results of studies requested in items 10 and 11 above.

13/ An adequate study is required to delinate the pharmacokinetic and pharmacodynamic aspect.

14/ These studies are to be conducted on the most toxic metabolite as determined from the results of a 60-day screening test for cholinesterase inhibition. This screening test is to be conducted on the following metabolites using the rat as the test species; phorate sulfoxide, phorate sulfone, phoratoxon sulfide, and phoratoxon sulfone. A reasonable number of animals is to be used in the screening tests. The lowest dose level tested in the 6-month studies must be low enough to establish a NOEL. Cholinesterase inhibition in plasma red blood cells and brain should be determined.

15/ A proposed protocol is to be submitted and approved by the Agency prior to initiating these studies.

16/ Collectively, these data fulfill the data requirement.

17/ The 21-day dermal study would be sufficient to assess the possible dermal exposure associated with the current pesticidal use of phorate.

*Data submitted by American Cyanamid. These data may be compensable.

TABLE A

GENERIC DATA REQUIREMENTS FOR PHORATE

	Data Requirement	Composition[1]/	Use [2]/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)[3]/
	§158.145 Wildlife and Aquatic Organisms					
71-1	Acute Avian Oral Toxicity	TGAI	A,B,C,F	yes	GS0103102 00020560 ** 05008363	no[12]/
71-2	Avian Subacute Dietary Toxicity					
	Waterfowl	TGAI	A,B,C,F[4]/	yes	00022923	no
	Upland gamebird	TGAI	A,B,C,F[4]/	yes	00022923	no
71-3	Wildlife Mammal Toxicity	TGAI	A,C	yes	GS0103103	no
71-4	Avian Reproduction	TGAI	A,C	no		yes
71-5	Simulated and Actual Field Testing For Mammals & Birds	TEP	A,C	partial	00074623* 00087553* 00084503* 00092832* 00074627* 00052237* 00074624* 00092834* 00074625* 00074626*	yes[8]/
	Secondary Poisoning Studies	TEP	A,C	No		yes[11]/
	Aquatic Organism Testing					
72-1	Fresh Water Fish Acute Toxicity					
	coldwater	TGAI	A,B,C,F[4]/	yes	GS0103111	no
	warmwater	TGAI	A,B,C,F[4]/	yes	GS0103111	no
		TEP[9]/	A,C	partial	GS0103104 GS0103105	yes[10]/
72-2	Acute Toxicity: Freshwater Invertebrates	TGAI	A,C,B,F	yes	GS0103111 05017538	no[13]/
		TEP[9]/	A,C	no		yes

TABLE A
GENERIC DATA REQUIREMENTS FOR PHORATE

Data Requirement		Composition1/	Use 2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)3/
§158.145 Wildlife and Aquatic Organisms (continued)						
72-3	Acute Toxicity to Estuarine and Marine Organisms fish 5/	TGAI	A,B,C	yes	GS0103106	no
	shrimp 5/	TGAI	A,B,C	yes	GS0103106	no
	mollusks 5/	TGAI	A,B,C	yes	GS0103106	no
		TEP9/	A,C	no		yes
72-4	Fish Early Life-Stage and Aquatic Invertebrate Life Cycle					
	estuarine	TGAI	A,C	partial	GS0103106	yes6/
	freshwater	TGAI	A,C	no		yes6/
72-5	Fish Life Cycle	TGAI	A,C	no		reserved7/
72-6	Aquatic Organism Accumulation	TGAI, PAI or Degradation Product	A,C,	no		reserved7/
72-7	Simulated or Actual Field Testing Aquatic Organisms	TEP	A,C	no		yes8/

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop: D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry: H=Domestic Outdoor; I=Indoor.

3/ Data must be submitted no later than 18 months from date of this Standard.

4/ For greenhouse use only one species tested is required with the TGAI to support the manufacturing-use product.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHORATE

§158.145 Wildlife and
Aquatic Organisms
(continued)

5/ Acute toxicity studies on estuarine fish, shrimp and mollusks are required for crops with significant acreage (>300,000 acres) in coastal counties.

6/ These studies are required based upon the laboratory bioassays and estimated/actual residues in the environment. The estuarine mysid shrimp life cycle test and sheepshead minnow embryo-juvenile test are deficient but can fulfull data requirements upon submission of additional data. Raw data must be submitted for the sheepshead minnow test so that the statistical analysis can be verified. The D.O. and pH measurements; and the raw data must be submitted for the mysid shrimp test so the effects on survivability and reproduction can be verified. Tests with freshwater organisms are also required.

7/ Pending results of lower-tier studies and environmental fate data.

8/ Based on the reported bird and fish kills and the concentrations of phorate in the environment, full field studies including population monitoring are required. Collectively the studies fulfill the simulated field study data requirement.

9/ TEP will likely be a granular formulation.

10/ The submitted studies were conducted with 600 E.C., and collectively the studies fulfill the data requirement for the E.C. formulation. A granular formulation must also be tested.

11/ Because of the high toxicity of the phorate oxidation metabolites, secondary poisoning studies are needed for one mammal and one avian species. A proposed protocol must be submitted and approved by the Agency prior to initiation of these studies.

12/ Collectively the studies fulfill the data requirement.

13/ The data cited as GS0103111 is sufficient to fulfill this data requirement.

* Data submitted by American Cyanamid. These data may be compensible.

** Data submitted by Stauffer Chemical Co. These data may be compensible.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHORATE

Data Requirement	Composition1/	Use 2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)
§158.155 Nontarget Insect					
NONTARGET INSECT TESTING - POLLINATORS:					
141-1 - Honeybee acute contact toxicity	TGAI	A,B	Yes	00036935 05001991	No
141-2 - Honeybee - toxicity of residues on foliage	TEP	A,B	No	________	No3/
141-3 - Wild bees important in alfalfa pollination - toxicity of residues on foliage	TEP	A	No	________	No3/
141-4 - Honeybee subacute feeding study	[Reserved]4/				
141-5 - Field testing for pollinators	TEP	A,B	No	________	No3/
NONTARGET INSECT TESTING - AQUATIC INSECTS:					
142-1 - Acute toxicity to aquatic insects	[Reserved]5/				
142-2 - Aquatic insects life cycle study	[Reserved]5/				

TABLE A
GENERIC DATA REQUIREMENTS FOR PHORATE

Data Requirement	Composition1/	Use 2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)
§158.155 Nontarget Insect (continued)					
142-3 - Simulated or actual field testing for aquatic insects	[Reserved]5/				
143-1 thru 143-3 - NONTARGET INSECT TESTING-PREDATORS AND PARASITES	[Reserved]5/				

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.

2/ The use patterns are coded as follws: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ Except for uses on bermudagrass grown for seed, as a cotton seed treatment, and as soil application to corn at planting, agricultural use of phorate is limited to granular formulations. As this precludes bee exposure, no additional data are required.

4/ Reserved pending development of test methodology.

5/ Reserved pending Agency decision as to whether the data requirement should be established.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PHORATE

§158.120-PRODUCT CHEMISTRY

Guideline Citation and Name of Test	Test Substance 1/	Guideline Status 2/	Are Data Required 3/ Yes	No
Product Identity:				
61-1 - Identity of Ingredients	TGAI	R	☒	☐
61-2 - Statement of Composition	TGAI	R	☒	☐
61-3 - Discussion of Formation of Ingredients	TGAI	R	☒	☐
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis	TGAI	CR	☒	☐
62-2 - Certification of Limits	TGAI	R	☒	☐
62-3 - Analytical Methods for Enforcement of Limits	TGAI	R	☒	☐
Physical and Chemical Characteristics				
63-2 - Color	TGAI	R	☒	☐
63-3 - Physical State	TGAI	R	☒	☐
63-4 - Odor	TGAI	R	☒	☐

: :

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PHORATE

§158.120-PRODUCT CHEMISTRY

Guideline Citation and Name of Test	Test Substance 1/	Guideline Status 2/	Are Data Required 3/ Yes	Are Data Required 3/ No	Footnot Number
Physical and Chemical Characterisics (continued)					
63-7 - Density, Bulk Density, or Specific Gravity	MP	R	☒	☐	
63-12- pH	MP	R	☒	☐	
63-14- Oxidizing or Reducing Action	MP	CR	☒	☐	
63-15- Flammability	MP	CR	☒	☐	
63-16- Explodability	MP	CR	☒	☐	
63-17- Storage Stability	MP	R	☒	☐	
63-18- Viscosity	MP	CR	☒	☐	
63-19- Miscibility	MP	CR	☒	☐	
63-20- Corrosion Characteristics	MP	R	☒	☐	
Other Requirements:					
6 - 1 - Submittal of samples	PAI	CR	☐	☒	

: :

DATA REQUIREMENT FOOTNOTES:

1/ Test Substance: MP =- Manufacturing-use product; PAI = Pure active ingredient
2/ R = required under the guideline; CR = conditionally required.
3/ Data must be submitted no later than 6 months from date of this Standard.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PHORATE

Data Requirement	Composition1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)
§158.135 Toxicology				
ACUTE TESTING				
81-1 - Acute Oral Toxicity - Rat	MP	Yes	05014313	No
81-2 - Acute Dermal Toxicity	MP	Yes	05014313	No
81-3 - Acute Inhalation Toxicity - Rat	MP	Yes	05014313	No
81-4 - Primary Eye Irritation - Rabbit	MP	No		No2/
81-5 - Primary Dermal Irritation	MP	No		No2/
81-6 - Dermal Sensitization	MP	No		No3/

1/ Composition: MP= manufacturing-use product.

2/ Phorate is too toxic to allow the use of the appropriate dose levels required for adequate testing.

3/ Testing is not required. In addition to the high acute toxicity, the chemical structure of phorate does not indicate a possible dermal sensitization potential.

TABLE C

PRODUCT SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS CONTAINING PHORATE

Data Requirement	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)[2/]
§158.135 Toxicology				
ACUTE TESTING				
81-1 - Acute Oral Toxicity - Rat	EP	No		Yes[3/]
81-2 - Acute Dermal Toxicity	EP	No		Yes[3/]
81-3 - Acute Inhalation Toxicity - Rat	EP	No		Yes[3/]

[1/] Composition: EP = end-use product.

[2/] Data must be submitted no later than 6 months from date of this Standard.

[3/] (a) For new end-use granular products containing less than 5.0% phorate: Either these data must be submitted and evaluated prior to registration or the products must be labeled for restricted use.

(b) For currently registered end-use granular products containing less than 5.0% phorate: These products must be labeled for restricted use pending receipt and evaluation of these data.

II. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA Section 3(c)(2)(B) and describes, in table format, the data required for maintaining the registrability of each product. Additionally, a bibliography (Appendix II-1) is included that identifies that data considered as part of the data base supporting this standard. EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA Section 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data [1] Must Be Submitted. You may ascertain which generic data you must submit by consulting Table A at the end of this chapter. That table shows all the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required data must be submitted and any necessary studies must be conducted in accordance with EPA-approved protocols, the Pesticide Registration Guidelines 2/, or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you wish not to develop data which are necessary to support the registration or reregistration of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

1/ Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

2/ The Pesticide Registration Guidelines were reproposed on November 24, 1982 in 47 Federal Register 53192.

Also for certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Chapter IV of this document.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix II-2] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

   (b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix II-3)*/

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*/ FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of

(Footnote continued at bottom of next page)

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may

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the agreement. The statute does not compel any registrant to agree to develop data jointly.

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

IV. SUBMISSION OF REVISED LABELING AND PACKAGING INFORMATION

Note: This section applies to end-use products only to the the extent described under Section I of this document. Otherwise, the following information pertains exclusively to manufacturing-use products.

The Agency requires applicants for registration or re-registration to ensure that each label (1) contains accurate, complete, and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients, and (2) incorporates labeling format and terminology which are sufficiently standardized to avoid user confusion.

As part of your application, you will be required to submit draft labeling consistent with: applicable product-specific data; the precautionary statements and use directions; and the regulations concerning classification [40 CFR §162.11(c)], packaging [40 CFR §162.16], and labeling [40 CFR §162.10, Appendix IV-1 an IV-2], as indicated by the following paragraphs of this chapter of the guidance document.

If owners of currently registered products fail to submit revised labeling and packaging information complying with this Section and/or Section II, EPA may issue a notice of intent to cancel the registration under FIFRA §6(b)(1).

A. Label Contents

40 CFR §162.10 (Appendix IV-1) requires that certain specific labeling statements must appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Tables D, E, and F (Appendix IV-2).

Item 1. PRODUCT NAME - The name, brand, or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. See Appendix IV-1. [40 CFR §162.10(b)]

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text. See Appendix IV-1. [40 CFR §162.10(c)]

Item 3. NET CONTENTS - A net content statement is required on all labels. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be stated in terms of weight, expressed as avoirdupois pounds and ounces, and stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces." In addition to the required units specified, net contents may be expressed in metric units. See Appendix IV-1. [40 CFR §162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix IV-1. [40 CFR §162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. See Appendix IV-1. [40 CFR §162.10(f)]

Item 6. INGREDIENT STATEMENT - An ingredient statement is required on the front panel and must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredient statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix IV-1. [40 CFR 162.10(g)]

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - All labels are required to have precautionary statements grouped together on the front panel, preferably within a block outline. The table below shows the minimum type size requirements on various size labels, as set forth in the Regulations.

Size of Label on Front Panel in Square Inches	Signal Word as Required Minimum Type Size All Capitals	"Keep Out of Reach of Children" as Required
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - All labels are required to have the statement "Keep Out of Reach of Children" located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix IV-1. [40 CFR §162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. See Appendix IV-1. [40 CFR §162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, inhalation, or dermal toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word poison. See Appendix IV-1. [40 CFR §162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix IV-1. [40 CFR §162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix IV-1. [40 CFR §162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix IV-1. [40 CFR §162.10 (h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions taken to avoid accident, injury or damage. See Appendix IV-1. [40 CFR §162.10 (h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. See Appendix IV-1. [40 CFR §162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix IV-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

    a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

    b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C) as determined by the method specified in 40 CFR §163.61-8(c)(13) (ii) of Subpart D.

    c. A "non-flammable aerosol" is one which meets the following criteria:

        i. The flame extension is zero inches, using the method specified in 40 CFR §163.61-8(c)(13)(ii);

ii. There is no flash back; and

iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C), determined by the method specified in 40 CFR §163.61-8(c)(13)(i).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "nonflammable (gas, liquid, etc.)" on the label.

   It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data submitted in accordance with 40 CFR §163.61-10(c) demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. PRODUCT CLASSIFICATION: CLASSIFICATION LABELING REQUIREMENTS AND COMPLIANCE SCHEDULE - Section 3(d) of FIFRA requires that all pesticide formulations/uses be classified for either general or restricted use, and that those uses classified as restricted be limited to use by certified applicators or persons under their direct supervision (or subject to such other restrictions as may be imposed by regulation).

In the Registration Standard, the Agency has: (1) indicated certain formulations/uses to be restricted, based either on a previous classification determination made through the optional procedures of 40 CFR §162.30 or based on data already available to the Agency, or (2) indicated certain formulations/uses to be unrestricted, based on data already available to the Agency, or (3) reserved any classification decision until appropriate short-term data are submitted. Uses have not been classified for general use at this time because such a decision requires an evaluation of chronic data, most of which has yet to be generated.

The product-specific data required by the Standard should be used by each registrant to make a classification determination following the criteria of 40 CFR §162.11(c) (Appendix V-4). The draft label(s) submitted to the Agency as part of your application should reflect this determination, and must be consistent with the terms of 40 CFR §162.10 and this guidance package with respect to label language and format for restricted use products. (No label changes with respect to classification are required for products with unrestricted uses.) The rationale supporting a classification proposal by the registrant that differs from a classification determination found in the Standard should be submitted with your application.

During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 162.11(c). You will be notified of the Agency's classification evaluation.

A. Classification Labeling Requirements

1. Unrestricted Uses - No label changes with respect to a classification statement are necessary for those formulations/uses that are unrestricted.

2. Restricted Uses - Pesticide products bearing directions for use for formulations/uses classified restricted shall bear statements of restricted use classification on the front panel as described below:

    a. Front panel statement of restricted use classification.

        i. At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in 40 CFR §162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

ii. Directly below this statement on the front panel, a summary statement of the terms of restriction shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

3. Some But Not All Uses Restricted - If you determine that some uses should be classified RESTRICTED and some uses should be unrestricted, several courses of action detailed below are available:

   i. You may delete all RESTRICTED uses and submit a draft label of the registration of your product to reflect only those uses that are unrestricted.

   ii. Unrestricted uses may appear on a RESTRICTED label, but not vice versa. Therefore you have the option of using a RESTRICTED USE label bearing all of your directions for use. If you choose this option, you may not distinguish those uses that are not unrestricted from those that are RESTRICTED.

   iii. You may register two separate products with identical formulations, one containing only unrestricted uses and the other RESTRICTED uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the product names will be assigned separate registration numbers.

B. Compliance Schedules

1. Unclassified uses - None.

2. Restricted uses - The compliance schedule for restricted use products is as follows:

No product with a use classified for restricted use under this standard may be released for shipment by the registrant or producer after September 1, 1985, unless such product bears the restricted-use classification. All products still in channels of trade after September 1, 1986, must be labeled for restricted-use.

Item 11A. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. Make certain that the statement you use pertains specifically to your product. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix IV-5 for the latest specific storage and disposal product label statements.

Item 11B. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix IV-1. [40 CFR §162.10]

B. Collateral Information

Bulletins, leaflets, circulars, brochures, data sheets, flyers, and other graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

V. INSTRUCTIONS FOR SUBMISSION

All applications prepared in response to this Notice should be addressed as follows:

Product Manager William H. Miller
Phone No. (703) 557-2600
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency

Washington, D.C 20460

For each product for which continued registration is desired:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA Form 8580-1. Refer to Appendix II-2 with appropriate attachments.

2. Within 6 months from receipt of this document registrants must submit:

    a. Confidential Statement of Formula, EPA Form 8570-4.

    b. Product Specific Data Report, EPA Form 8580-4 (Appendix III-1).

    c. Two copies of any required product-specific data.

    d. Two copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this guidance document and the results of the short-term data, the registrant may submit such labeling. (End-use product labeling needs to comply specifically with the instruction in Section II of this guidance document.) The labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for stortage in 8-1/2 x 11 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.

3. Within the time set forth in Table A, all generic data must be submitted by the affected registrant(s).

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notify the Product Manager listed above.

After the Supreme Court has ruled on the Union Carbide Decision, you will be informed as to when you must submit your Application for Amended Pesticide Registration (EPA Form 8570-1) and the associated data support information.

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LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (REFER TO THE SAMPLE LABELS FOLLOWING)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Est. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & cross-bones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following statement of classification or ahead of directions for use		
10A	Re-entry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use.
10D U.S.	Directions for use	All products	None	None	May be in metric as well as U.S. units

PRODUCT SPECIFIC DATA REPORT

EPA Registration No.________________Guidance Document for____________________________

Date______________________________

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				

63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

Appendix IV-3

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

Appendix IV-5

STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading must appear in the minimum type size listed below:

Size of label front panel in square inches	Required type size for the heading STORAGE AND DISPOSAL (all capitals)
10 and under	.6 point
Above 10 to 15	.8 point
Above 15 to 30	10 point
Over 30	12 point

Storage and disposal instructions must be set apart and clearly distinguishable from other directions for use. Blocking storage and disposal statements with a solid line is suggested as a means of increasing their prominence.

A. Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.
2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.
3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

   "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

   The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

Container Type	Statement
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1] Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

2. The labels for all other products must bear container disposal instructions, based on container type, listed on the first page of this Appendix.

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List) Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
0,0-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
    (disulfoton, Di-Syston)
0,0-Diethyl 0-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
0,0-Dimethyl 0-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
0,0,0,0-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

There are currently no inert ingredients for commercial pesticides on the "Acutely Hazardous" List (RCRA "E" List).

Appendix IV-5
(continued)

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)pthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one
    (kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide,Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

"Toxic" Commercial Pesticide Products (RCRA "F" List) Active Ingredients:

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphorodithioic acid, 0,0-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene